

# EXHIBIT 2

## UNITED STATES DISTRICT COURT

for the  
District of Delaware

Apple Inc.

*Plaintiff*

v.

Masimo Corporation and Sound United, LLC

*Defendant*

Civil Action No. 22-cv-1378-MN-JLH

## SUBPOENA TO TESTIFY AT A DEPOSITION IN A CIVIL ACTION

To:

Philips North America LLC., 222 Jacobs Street, Cambridge, MA 02141  
c/o Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808*(Name of person to whom this subpoena is directed)*

☒ **Testimony:** YOU ARE COMMANDED to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization, you must promptly confer in good faith with the party serving this subpoena about the following matters, or those set forth in an attachment, and you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about these matters:

SEE ATTACHMENT A

Place: Regus, Prudential Tower 800 Boylston Street, 16th Floor Boston, MA 02199	Date and Time: 08/09/2023 10:00 am
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The deposition will be recorded by this method: Stenographically, audiotaped, and videotaped

☒ **Production:** You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and must permit inspection, copying, testing, or sampling of the material:

See Schedule A (attached). Documents to be produced on or before July 21, 2023, to:  
Jamie Kringstein, Desmarais LLP, 230 Park Avenue, New York, NY 10169  
jkringstein@desmaraisllp.com

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 07/06/2023

CLERK OF COURT

OR

/s/ Jamie L. Kringstein

*Signature of Clerk or Deputy Clerk**Attorney's signature*

The name, address, e-mail address, and telephone number of the attorney representing *(name of party)* Plaintiff Apple Inc.

, who issues or requests this subpoena, are:  
Jamie Kringstein | Desmarais LLP | 230 Park Ave., New York, NY 10169 | 212-808-2921 | jkringstein@desmaraisllp.com

**Notice to the person who issues or requests this subpoena**

If this subpoena commands the production of documents, electronically stored information, or tangible things before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

Civil Action No. 22-cv-1378-MN-JLH

**PROOF OF SERVICE**

*(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)*

I received this subpoena for *(name of individual and title, if any)* \_\_\_\_\_  
on *(date)* \_\_\_\_\_ .

☐ I served the subpoena by delivering a copy to the named individual as follows: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_ on *(date)* \_\_\_\_\_ ; or

☐ I returned the subpoena unexecuted because: \_\_\_\_\_  
\_\_\_\_\_ .

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also  
tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of  
\$ \_\_\_\_\_ .

My fees are \$ \_\_\_\_\_ for travel and \$ \_\_\_\_\_ for services, for a total of \$ 0.00 .

I declare under penalty of perjury that this information is true.

Date: \_\_\_\_\_  
\_\_\_\_\_  
*Server's signature*

\_\_\_\_\_  
*Printed name and title*

\_\_\_\_\_  
*Server's address*

Additional information regarding attempted service, etc.:

**Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)****(c) Place of Compliance.**

**(1) For a Trial, Hearing, or Deposition.** A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

- (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
- (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
  - (i) is a party or a party's officer; or
  - (ii) is commanded to attend a trial and would not incur substantial expense.

**(2) For Other Discovery.** A subpoena may command:

- (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
- (B) inspection of premises at the premises to be inspected.

**(d) Protecting a Person Subject to a Subpoena; Enforcement.**

**(1) Avoiding Undue Burden or Expense; Sanctions.** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

**(2) Command to Produce Materials or Permit Inspection.**

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

- (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.
- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

**(3) Quashing or Modifying a Subpoena.**

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

- (i) fails to allow a reasonable time to comply;
- (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
- (iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

- (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
- (ii) ensures that the subpoenaed person will be reasonably compensated.

**(e) Duties in Responding to a Subpoena.**

**(1) Producing Documents or Electronically Stored Information.** These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

**(2) Claiming Privilege or Protection.**

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

- (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

**(g) Contempt.**

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.



# ATTACHMENT A

## **SCHEDULE A**

### **DEFINITIONS**

The following terms shall have the meanings set forth below whenever used in any Definition, Instruction, Request for Production, or Deposition Topic.

1. As used herein, the terms “Philips,” “You,” or “Your” means Philips Electronics North America Corporation, Respiroics Novamatrix LLC, Respiroics, Inc., Novamatrix Medical Systems, BioTelemetry, Inc., LifeWatch Technologies Ltd., LifeWatch Inc., HP Healthcare, and all of their predecessors (merged, acquired, or otherwise), successors, subsidiaries, divisions, departments, and affiliates thereof, and all officers, directors, principals, agents, employees, attorneys, and other persons acting on their behalf.

2. As used herein, “Apple” means Apple Inc., all of its predecessors (merged, acquired, or otherwise), successors, subsidiaries, divisions, departments, and affiliates thereof, and all officers, directors, principals, agents, employees, attorneys, and other persons acting on their behalf.

3. As used herein, “Masimo” means Masimo Corporation, Cercacor Laboratories, Inc., and all their predecessors (merged, acquired, or otherwise), successors, subsidiaries, parents, sisters, divisions, departments, partnerships, and affiliates thereof, and all of their officers, directors, principals, agents, employees, independent contractors working under their control, attorneys, and other persons acting on their behalf.

4. As used herein, “Masimo Asserted Patents” means U.S. Patent No. 10,687,743 (“the ’743 Patent”), U.S. Patent No. 10,722,159 (“the ’159 Patent”), U.S. Patent No. 8,190,223 (“the ’223 Patent”), U.S. Patent No. 10,736,507 (“the ’507 Patent”), and U.S. Patent No. 10,984,911 (“the ’911 Patent”).

5. As used herein, “Relevant Date” means September 20, 2012.

6. As used herein, “Exhibits” means Exhibits 1-4 attached hereto.

7. As used herein, “Blood Oxygen and Heart Rate Features” means the product feature(s) relating to monitoring, measuring, sensing, detecting, and/or obtaining blood oxygen (SpO2) and/or heart rate measurements, including all hardware, software, firmware, components, modules, applications, and devices involved in such features, that were made or sold before the Relevant Date.

8. As used herein, “Product” means any machine, manufacture, apparatus, device, system, process, service, method, or instrumentality which is designed to function together electrically, mechanically, chemically, or otherwise, to achieve a particular function or purpose, including those offered for sale, sold, imported, or under development.

9. As used herein, “Relevant Products” means (1) the Philips IntelliVue MX40, (2) the LifeWatch V, (3) the Novamatrix 7300, (4) the HP Medical M-Series pulse oximetry sensors (including, for example, the HP M1191A, M1192A, M1193A, and M1194A), (5) Philips IntelliVue Information Center iX software, (6) the products described in Exhibits 1-4, (7) any Product made or sold by or for You having Blood Oxygen and Heart Rate Features before the Relevant Date, (8) any related Products or modules having Blood Oxygen and Heart Rate Features before the Relevant Date, and (9) any other software programs, applications, or modules that display Blood Oxygen or Heart Rate from the Relevant Products.

10. As used herein, “Source Code” means any human-readable programming language or format that defines software, firmware or integrated circuits, including but not limited to, computer code, scripts, assembly, binaries, object code, Register Transfer Level (“RTL”) descriptions, VHDL, Verilog, and other Hardware Description Language (“HDL”) formats.

11. The term “Third Party” means any person or entity other than You, Masimo, or Apple.

12. As used herein, the term “document” shall have the full meaning ascribed to it by the Federal Rules of Civil Procedure and includes the original and every non-identical copy or reproduction in Your possession, custody, or control, and further is used in a broad sense to refer to any electronically stored information (“ESI”) or any tangible object or thing that contains, conveys, or records information.

13. As used herein, the singular of any word shall include the plural, and the plural shall include the singular.

14. As used herein, “person” means any natural person or any business, legal, or governmental entity or association.

15. As used herein, “include” and “including” shall be construed to mean “without limitation,” so as to give the broadest possible meaning to interrogatories and definitions containing those words.

16. As used herein, “and” and “or” shall be construed conjunctively and disjunctively so as to acquire the broadest meaning possible.

17. As used herein, “any” and “all” shall each be construed to mean “each and every,” so as to acquire the broadest meaning possible.

18. As used herein, the singular of any word shall include the plural, and the plural shall include the singular.

19. As used herein, “related” or “relating” to any given subject means, without limitation, identifying, describing, discussing, concerning, assessing, stating, reflecting

constituting, containing, embodying, tending to support or refute, or referring directly or indirectly to, in any way, the particular subject matter identified.

20. As used herein, “identify” as applied to a document shall mean to specify: (a) the type of the document (i.e., whether it is a letter, memorandum, e-mail, etc.); (b) the document’s title and general subject matter; (c) the number of pages of the document; (d) the date the document was prepared; (e) the name of each and every author, addressee, distributor, and recipient of the document; (f) the date each distributor distributed the document and the date each recipient received the document; and (g) the name of each person that has or had possession, custody, or control of the document.

21. Any term not specifically defined herein shall be defined in accordance with normal usage as well as with the Federal Rules of Civil Procedure and the Local Rules of the United States District Court for the District of Delaware.

**INSTRUCTIONS FOR REQUESTS FOR PRODUCTION**

1. Apple's Requests for Production seek responsive documents and information sufficient to answer each of the Requests that are known or available to You or in Your possession, custody, or control. If, after exercising due diligence to secure the documents or information requested, You cannot fully respond to a Request for Production, state that such is the case and answer to the fullest extent possible, stating what responsive documents or information are available, what documents or information cannot be provided, why the documents or information are unavailable, and what efforts were made to obtain the unavailable documents or information. If documents or information responsive to a Request in this subpoena are in Your control, but not in Your possession or custody, promptly identify the entity with possession or custody.

2. Regardless of whether a production is in electronic or paper format, documents that were maintained together before production should be produced in the same form, sequence, organization, or other order or layout as they were maintained, including any labels, file folders, file jackets, covers, or containers in which such documents are located or with which such documents are associated. If copies of documents are produced in lieu of the originals, such copies should be legible and bound or stapled in the same manner as the original.

3. These Requests for Production shall be deemed continuing. Documents located, and information learned or acquired, at any time after Your response is due must be promptly supplemented at the place specified in this subpoena.

4. A copy of the Protective Order entered in this Action for the protection of any requested proprietary, confidential, or commercially sensitive information is attached hereto.

### **REQUESTS FOR PRODUCTION**

1. Documents sufficient to identify and describe the functionality, features, and operation of the Blood Oxygen and Heart Rate Features of the Relevant Products and all components, modules, applications, hardware, software, and firmware contained therein, including, without limitation, user manuals, brochures, presentations, user guides, product literature, engineering specifications, circuit diagrams, architectural diagrams, bills of materials, technical manuals, product specifications, data sheets, laboratory notebooks, research papers, test data and results, analyses, invention disclosure forms, reports, service manuals, operator's manuals, implementation guides, white papers, product tutorials, and non-public documentation.

2. Documents sufficient to identify and describe the conception, design, research, development, testing, use, operation, maintenance, marketing, modifying, sale, offer for sale, and supply of the Relevant Products, including the persons and entities involved.

3. Documents, communications, and things comparing the Apple Watch to the Relevant Products.

4. Other versions of the Exhibits and documentation related to the Exhibits.

5. Documents sufficient to show the earliest dates that each of the Relevant Products were first conceived; reduced to practice; and made, sold, used (including by third parties such as end users), offered for sale, in public use, and otherwise available to the public in the United States, including but not limited to documents relating to any conference, seminar, exhibition, convention, or trade show at which such Product is or was discussed, referred to, advertised, displayed, demonstrated, or shown, such as, without limitation, product specifications, catalogs, announcements, advertisements, brochures, articles, pamphlets, price lists, invoices, purchase orders, sales records, or other promotional, marketing, or sales materials.

6. Publications related to the Relevant Products that were made available to the public.

7. Three samples of each Relevant Product.
8. Source Code sufficient to show the functionality of the Blood Oxygen and Heart Rate Features of the Relevant Products.
9. Documents sufficient to show the authorship and authenticity of all the documents produced in response to this subpoena.



**DEPOSITION TOPICS**

1. The functionality, features, and operation of the Blood Oxygen and Heart Rate Features of the Relevant Products.

2. The earliest dates that each Relevant Product was reduced to practice, made, sold, offered for sale, in public use, or otherwise available to the public.

3. The subject matter contained within the documents produced in response to Requests For Production herein, including the authentication thereof.

4. The authorship and authenticity of the documents produced in response to the Requests For Production herein.

# EXHIBIT 1



# IntelliVue MX40

Instructions for Use

Release B.0

**PHILIPS**



## **Notice**

### **Proprietary Information**

This document contains proprietary information, which is protected by copyright.

First Edition 2012

4535 643 15721

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This product contains software licensed under an open source license. For acknowledgments, license texts and source code, please refer to the IntelliVue Information Center iX M3290B Software \References \README.pdf.

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Tone modulation is licensed under US patent 4,653,498 from Nellcor Puritan Bennett Incorporated.

### **Manufacturer**

Philips Medical Systems  
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Andover, MA 01810-1099

(978) 687-1501

Printed in USA



## **Document Number**

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## **Warranty**

The information contained in this document is subject to change without notice. Philips Medical Systems makes no warranty of any kind with regard to this material, including, but not limited to, the implied warranties or merchantability and fitness for a particular purpose. Philips Medical Systems shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance, or use of this material.

## **FCC**

This device complies with Part 15 and/or Part 95 of the FCC Rules. Operation is subject to the following two conditions: (1) these devices may not cause harmful interference, and (2) these devices must accept any interference received, including interference that may cause undesired operation.

Changes and modifications not expressly approved by Philips Medical Systems can void your authority to operate this equipment under Federal Communications Commission's rules

## **Protecting Personal Information**

It is recommended that customers have policies and procedures for the proper handling of personal or sensitive information, ePHI (electronic protected health information) and PHI (protected health information), which will maintain the confidentiality, integrity, and the availability of these types of data. Any organization using this product should implement the required protective means necessary to safeguard personal information consistent with each applicable country law, code and regulation; and consistent with their developed and maintained internal policies and procedures.

While handling personal information is outside the scope of this document; in general, each organization is responsible for identifying:

- Who has access to personal data and under what conditions an individual has authorization to use that data.
- What security controls are in place to protect personal and sensitive data.
- How the data is stored and the conditions by which it is stored.
- How the data is transmitted and the conditions under which that data is transmitted.

Protecting personal health information is a primary component of a security strategy. Personal and sensitive information should be protected according to the applicable laws, regulations and directives, such as HIPAA, PIPEDA and/or Council of the European Union security and privacy rules.

## **Compliance**

Uses of the system for purposes other than those intended and expressly stated by the manufacturer, as well as incorrect use, incorrect operation, or modifications made to the system without explicit approval from Philips, may relieve the manufacturer (or his agent) from all or some responsibilities for resultant noncompliance, damage or injury.

## **Printing History**

New editions of this document will incorporate all material updated since the previous edition. Update packages may be issued between editions and contain replacement and additional pages to be merged by a revision date at the bottom of the page. Note that pages which are rearranged due to changes on a previous page are not considered revised.

The documentation printing date and part number indicate its current edition. The printing date changes when a new edition is printed. (Minor corrections and updates which are incorporated at reprint do not cause the date to change.) The document part number changes when extensive technical changes are incorporated.

First Edition February 2012

## **Document Conventions**

In this guide:

### **Warnings**

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#### **Warning**

A Warning alerts you to a potential serious outcome, adverse event or safety hazard. Failure to observe a warning may result in death or serious injury to the user or patient.

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## **Cautions**

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### **Caution**

A Caution alerts you to where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly in a remote risk of more serious injury.

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## **Notes**

A Note contains additional information on the product's usage.



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# 1. Introducing the IntelliVue MX40

This section introduces the IntelliVue MX40 wearable patient monitor.

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## MX40 Features

- Easy for clinicians to use and comfortable for patients to wear.
- 2.8" color, touch sensitive display.
- Smart, multi-measurement cable system available for use with reusable and single-patient use supplies.
- FAST SpO<sub>2</sub> (continuous, automatic or manual measurement).
- Standard, EASI or Hexad ECG lead system selection.
- Impedance-based Respiration measurement.
- 6-lead with two V-leads for diagnosing multiple cardiac abnormalities, including wide-QRS complex tachycardias and acute myocardial ischemia/infarction.
- Local measurement trend/alarm history.
- Local alarming for measurements (requires IntelliVue Information Center Release N or later or IntelliVue Information Center iX).
- Integrated radio for connection to an Information Center iX.
- Integrated short-range radio.
- Communication with IntelliVue Patient Monitors and Cableless Measurements via short-range radio connection (MP5/MP5T/MP5SC, MP2 and X2 monitors only).
- Powered by three AA batteries or rechargeable lithium-ion battery pack.

**Note** — The WLAN MX40 (Model Number 865352) is powered only by the rechargeable lithium ion battery pack.

- Audio feedback for out-of-range and lost device.
- Battery gauge on device and at Information Center.
- Alarm suspend and resume from standby at device and Information Center.
- Pouch with clear front that closes securely.

**Note** — Unlike a traditional bedside monitor which operates on AC power, the MX40 is powered by battery and provides time-limited screen display and local alarming.

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## **MX40 Models**

The MX40 is available in three models (ECG only, ECG and FAST SpO<sub>2</sub>, or ECG and SpO<sub>2</sub> Ready (for future upgrade)).

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## MX40 Release B.0 Compatibility

The MX40 is compatible for use with IntelliVue Information Center Release N and IntelliVue Information Center iX Release A. Limited compatibility is offered when used with IntelliVue Information Center Release L or M. See the "Operating with Release L or M" chapter for more information.

The MX40 is compatible for use with IntelliVue Patient Monitors Release G or later when wirelessly connected.

The MX40 is compatible for use with IntelliVue Cableless Measurements Release A.1.

The MX40 is compatible for use with Access Point Controller 862147, Release B.00.19 and Access Point Controller 865346, Release C.00.04.

The MX40 Patient Cable is compatible for use with IntelliVue Patient Monitor platforms MP2/X2, MP5/MP5T/MP5SC, MP20/30 with MMS or X2, MP40/50 with MMS or X2, MP60/70 with MMS or X2, MP80/90 with MMS or X2, and MX800/700/600 with MMS or X2.

## 2. What's New?

This section lists the most important new features and improvements to the MX40 and its user interface. Further information is provided in other sections of this book.

You might not have all of these features, depending on the MX40 configuration purchased by your hospital.

New Features and Enhancements.....	2-2
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## New Features and Enhancements

- **Compatibility**

The MX40 B.0 offers compatibility with the new IntelliVue Information Center iX

- **Respiration**

The MX40 now offers a Respiration Rate measurement (available with the IntelliVue Information Center iX only).

- **Rotating Alarm Presentation**

When multiple alarms are active, the MX40 will rotate the display of the alarm message every three seconds (Only INOPS are displayed with IntelliVue Information Center Release L or M).

- **Numeric Only Display**

A new display orientation is available showing six numerics only. No waveforms are shown (available with IntelliVue Information Center iX).

- **ECG Waveform Size Adjustment**

The size of the ECG waveform can now be adjusted by touching the waveform on the display.

- **Wireless LAN Availability**

The MX40 is now available as a Wireless LAN device for 802.11 a/b/g communication (for use with IntelliVue Information Center iX only).

- **ST and QT Measurement Analysis**

ST and QT values can be displayed on the MX40 (available with IntelliVue Information Center iX only).

- **Hexad**

A 12-lead ECG derived from a 6-wire electrode leadset is available to increase patient comfort and reduce interference (available with IntelliVue Information Center iX only).



## 3. Product Safety

This section consolidates the general safety warnings associated with the IntelliVue MX40. These warnings are repeated throughout the book in context where relevant.

Safety symbols and other markings on the MX40 are also described here.

General Safety .....	3-2
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## General Safety

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### Warnings

The MX40 operates exclusively via a wireless network connection, therefore, it should not be used for primary monitoring in applications where momentary loss of the ECG is unacceptable at the Information Center. It sends ECG and optionally pulse oximetry data to the Information Center, where the Information Center displays real-time patient data, provides alarm annunciation, data storage and review applications. The ECG waveform data, alarms and optionally SpO<sub>2</sub> can always be viewed on the MX40 regardless of the connection to the Information Center.

A wireless patient monitoring system will never be as reliable as a patient monitoring system that transmits its signal through a wire, due to the inherent nature of radio frequency and the many variables that affect over-the-air communication. This factor should be considered when electing to monitor patients using wireless technologies. If occasional loss of ECG monitoring at the Information Center is not clinically acceptable for certain patients, alternatives must be sought. As the IntelliVue MX40 does not provide a wired network connection, we would recommend the use of an IntelliVue patient monitor with a wired connection to the Information Center for these patients.

- For continued safe use of this equipment, it is necessary that the listed instructions are followed. Instructions in this manual in no way supersede established medical procedures.
- Do not touch the patient, or table, or instruments, during defibrillation. The battery door must be closed during defibrillation. These steps protect the clinician from high defibrillator voltage.
- This device is not to be used in the vicinity of electrosurgical units because such use may interrupt or interfere with the transmission of signals from the MX40.
- This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, or with oxygen or nitrous oxide.
- This equipment is not suitable for use in an MRI environment.
- Do not use patient cables with detachable lead wires that have exposed male pins. Electrocution could result if these pins are plugged into AC power.
- Do not use patient cables or accessory cables and sensors if prior visual inspection reveals cable damage or the presence of liquid, lint or dust inside.

- The system is not completely immune from radio interference although it is designed to minimize interference. Sources of interference that may be a problem include failing fluorescent lights and construction equipment. See "Electromagnetic Compatibility p. 15-8". The product should not be used next to or stacked with other equipment. If you must stack the product, you must check that normal operation is possible in the necessary configuration before the product is used on patients.
  - Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level during patient monitoring may result in patient danger. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.
  - If the MX40 enters a continuous "boot-up" cycle or the main display does not appear or update, ensure that you are using a freshly charged lithium-ion battery or new disposable batteries. If the batteries are fresh and the device reboots or does not update, remove the device from service and contact your service personnel.
  - Place the MX40 in a pouch or over clothing, or both, during patient use. The device should not touch the patient's skin during use.
  - Patients should be instructed not to open the battery compartment while the MX40 is in use.
  - Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement satisfactory maintenance as needed may cause undue equipment failure and possible health hazards.
  - Because the coverage range of Access Points can sometimes overlap, including different floor levels, the IntelliVue Device Location feature is not intended for use when attempting to locate a patient.
  - Short-range radio connections are subject to interruption due to interference from other radio sources in the vicinity, including microwaves, bluetooth devices, and DECT phones. Outside the frequency band and 5% above and below, i.e. the exclusion band according to IEC 60601-1-2, the short-range radio connection is immune up to 3V/m in the frequency range from 80MHz to 2.5 GHz. Depending on the strength and duration of the interference, the interruption may occur for an extended period. Any interruption of the signal due to interference, moving out of range, or for other reasons is indicated with a Tele Disconnected INOP message on the IntelliVue Patient Monitor.
-

General Safety

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**Caution**

Philips recommends that when using a pouch to attach the MX40 to your patient that you consider your patient's condition and are careful about placement of the straps as the straps could present a strangulation hazard.










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## Safety Symbols & Other Marks





The table below describes the safety symbols and other markings present on the MX40 and the lithium-ion battery.

Label	Definition
FCC ID: IC:	<b>Federal Communications Commission (FCC) ID</b> <b>Industry Canada Number</b>
GMDN:	<b>Global Medical Device Nomenclature</b>
	<b>Federal Communications Commission (FCC)</b> <b>Declaration of Conformity</b>
	<b>Rechargeable Battery</b>
	<b>CE Mark (MX40)</b> Compliance to Council Directive 93/42/EEC (Medical Device Directive) and 1995/5/EC (Radio Equipment and Telecommunications Equipment Directive) Symbol for Class 2 Radio Equipment
	<b>CE Mark (Rechargeable Lithium-ion Battery)</b> Compliance to Council Directive 2004/108/EC (EMC Directive)
	<b>Non-Ionizing Radiation</b> Interference to electronic equipment may occur in the vicinity of devices marked with this symbol.

Safety Symbols & Other Marks

Label	Definition
	<b>Disposal</b> Dispose of in accordance with the local country's requirements. 2002/96/EC (Waste Electrical and Electronic Equipment).
	<b>Follow operating instructions.</b>
<b>Rx</b>	<b>Prescription Device</b>
	<b>CSA Mark for</b> Certified by CSA to the applicable Canadian and US standards..
	<b>Defibrillation Proof</b> Patient connections are protected against defibrillation (DEFIBRILLATION-PROOF) and are a TYPE CF APPLIED PART.
<b>Service #:</b>	<b>Service Identification Number</b> Used to identify the equipment during a call to Philips Healthcare (Service)
	<b>Serial Number</b> Used to identify the equipment during a call to the Philips Healthcare (Service).
	<b>Reference Number</b> Indicates Philips Product Number
	<b>MAC Address</b>
	<b>Manufacturer and Date of Manufacture</b>
	<b>Battery Polarity</b>

Safety Symbols & Other Marks

Label	Definition
	<b>IPX Waterproof Rating</b> Protected against the effects of temporary immersion in water.
	<b>2D Barcode</b>
	<b>UL Listed Device</b> Listed by Underwriters Laboratories
	<b>Attention!</b> See <i>Instructions for Use</i> .

Safety Symbols & Other Marks



## 4. Basic Operation

This section gives you an overview of the IntelliVue MX40 and its functions. It tells you how to perform tasks that are common to all measurements, such as turning a measurement on and off, adjusting wave size and information in preparation for use.

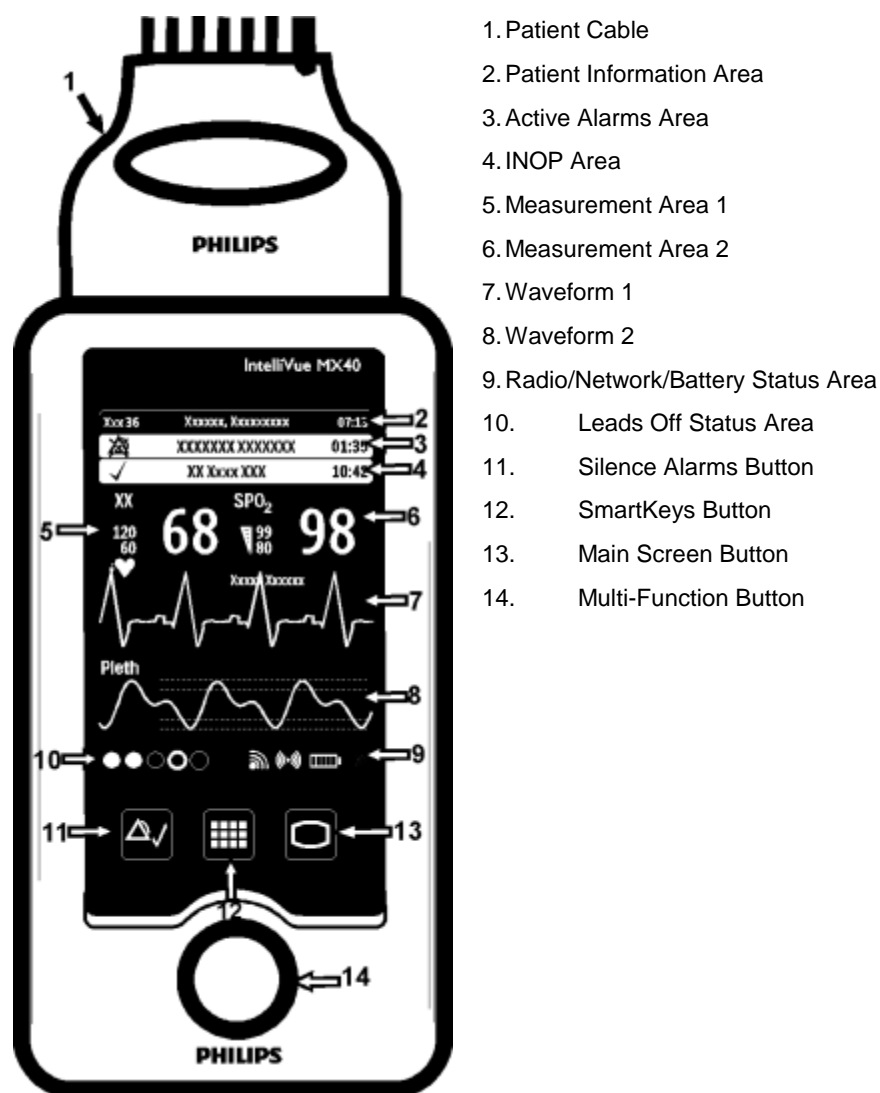
Familiarize yourself with all instructions including warnings and cautions before starting to monitor patients. Read and keep the Instructions for Use that come with any accessories as these contain additional important information.

Controls, Indicators and Connectors .....	4-2
Operating and Navigating .....	4-8
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## Controls, Indicators and Connectors

This section describes the clinical controls of the IntelliVue MX40. These controls include buttons, display icons, visual and auditory indicators, ports, and safety labeling located on the front and back of the device.


### MX40 Controls and Indicators




## Multi-Function Button

Button	Function
	<p>Depending on configuration at the Information Center:</p> <ul style="list-style-type: none"><li>• generates a Nurse Call;</li><li>• Initiates a Delayed Recording;</li><li>• Both, or;</li><li>• None</li></ul> <p><b>Note</b> — the Multi-Function Button does not operate when paired with an IntelliVue Patient Monitor via the short-range radio connection.</p>


## Silence Alarm Button

Button	Function
	<ul style="list-style-type: none"><li>• Initiates a local silence/acknowledgment of all active alarms when enabled (IIC).</li><li>• Initiates a global silence/acknowledgment of all active alarms when enabled (IIC iX).</li><li>• Silences the "Find Device" sound.</li></ul> <p><b>Note</b> — Alarms at the MX40 can be silenced from the Information Center. When silenced from the Information Center, the alarm sound is not silenced at the Information Center until it receives feedback from the MX40. This may take several seconds.</p>

## SmartKeys Button

Button	Function
	<p>Displays the SmartKey Menu on the touch screen.</p>

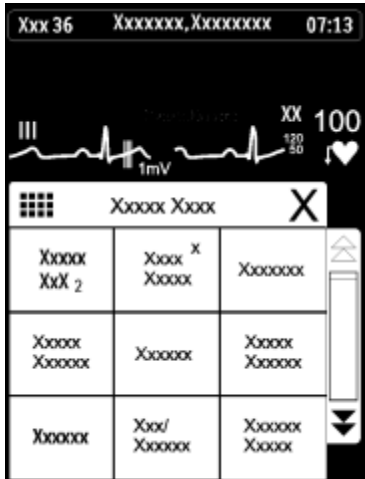
## Main Screen Button

Button	Function
	<ul style="list-style-type: none"> <li>• Activates the Touch Display if touched for two seconds.</li> <li>• Cycles through the display screens if touched repeatedly.</li> <li>• Resumes from Standby.</li> <li>• When pressed from a sub-menu, returns display to the Main Screen.</li> </ul>

## SmartKeys


The following table lists the SmartKeys available on the display of the MX40.


**Note**—gray text on a SmartKey signifies that the item is unavailable.

	SmartKey	Function
	Start SpO <sub>2</sub> <b>Note</b> — This SmartKey is unavailable when SpO <sub>2</sub> mode is continuous.	Starts a manual SpO <sub>2</sub> measurement.
	Delay Record	Starts a delayed recording at the Information Center.
	Alarms	Alarm Volume setting. Review of up to 50 previous alarm conditions (entries are stored during power cycle). Pause Alarms for configured time period (if enabled at the Information Center).
	Mode: Telemetry / Mode: Monitor	Toggles between modes. In Telemetry Mode, display and audio are off; in Monitor Mode, display and audio are always on.

	SmartKey	Function
	Standby	Puts the device into Standby locally and at the Information Center. Displays purchased/enabled product options. To resume from Standby, touch the Main Screen button.
	Add/Remove	Displays available monitors and IntelliVue Cableless Measurements to assign to via the short-range radio.
	Print Reports	Prints the pre-configured report as designated at the Information Center.
	Vitals Trends	View up to 24 hours of tabular trend data. One hour standard. 24 hours optional.
	Setup Screen	Determines time period that the display remains active after user interaction or whether the display is always On or always Off.
	Lock/Unlock	Locks/Unlocks the display.
	Op Mode	Selects either Monitoring, Demo, Config or Service modes.

## Alarms Area



- The Alarm Area of the MX40 displays physiological alarms and technical alarms.
- A multiple alarm indicator (down arrow) is displayed when multiple alarm conditions are present and the alarm message rotates every 3 seconds.
- A check mark in front of the alarm text signifies that the alarm has been acknowledged by touching the Silence Alarms button.
- Alarm Indicators display in the Patient Information Area in place of the time clock when alarm/INOP conditions are present but have not been acknowledged.
- Touching the Alarms Area displays a list of all active alarms.
- The alarms paused icon communicates whether the alarm system is on/off.
- Local Alarm Audio is off when the alarm volume symbol  is present next to the time..

## Patient Information Area

<b>Xxx 36</b>	<b>XXXXXXXX,XXXXXXXX</b>	<b>07:13</b>
---------------	--------------------------	--------------

The Patient Information Area displays the following information:




- Bed Label
- Patient Name (up to 15 characters will display)
- Time

Touching the Patient Information Area displays the **Patient Demogr.** menu which lists the following:


- Patient Name (Last, First, Middle)
- Lifetime ID
- Encounter ID
- Patient Category
- Paced Mode
- Height
- Weight
- Date of Birth
- Gender
- 

**Note** — If you use an alternative ID, it will display at the Information Center and on printed reports. It will not display at the MX40.

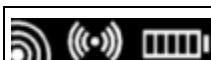
## Paced Status

  	<p>1. Pacing algorithm is on.</p> <p>2. Pacing algorithm is off.</p> <p>3. Pacing algorithm is on. Patient's paced status is unknown.</p>
--	---

## Display Lock

	<p>The Lock symbol appears in the lower left of the display when the MX40 is in a locked state after five minutes of non-use. Locking the display provides additional protection against accidental patient access. The display is unlocked using the SmartKeys menu.</p>
---	---

## Status Area



The status area of the MX40 displays short-range radio connection (optional) and system wireless connection status. You can also view battery strength for the type of battery used in the device, AA or rechargeable Li-on.

---

## Operating and Navigating

The principle method of operating your MX40 is via the Touch Display. Almost every element on the display is interactive. Display elements include measurement numerics, information fields, alarm fields, waveforms, SmartKeys and menus.

### Power-On Self Test

Once battery power is supplied, the MX40 performs a power-on self test to check operational status prior to start-up. Should a failure be detected, an INOP tone will sound and if possible, the appropriate INOP message for the failure will be communicated to the Information Center and displayed locally.

A successful power-on self test will then transition the MX40 to the start-up screen. Selectable background colors can be configured and display on the screen for assistance with device identification. This can be helpful when devices are in a pooled use setting.

If the MX40 enters a continuous "boot-up" cycle or the main display does not appear or update, ensure that you are using a freshly charged lithium-ion battery or new disposable batteries. If the batteries are fresh and the device reboots or does not update, remove the device from service and contact your service personnel.

You must visually check that a waveform is present on the display. You can access further status information by touching the status area on the display.

### Navigating

Touching the Navigation Bar on the right of the display will scroll through additional display items. Solid downward arrows indicate there are additional elements that are not currently displayed. The arrows briefly illuminate when touched. Your selection from the menu also illuminates when touched.



## Selecting Display Elements

Touch a display element to get to the actions linked to that element. For example, touch the Patient Information element to call up the Patient Info window, or touch the HR numeric to call up the Setup ECG menu. Touch the ECG waveform to call up the wave selection menu.

## Locking the Display

To provide additional protection against accidental patient access to the MX40, the display can be locked using the **Lock SmartKey**. When **Lock** is selected, the **SmartKey** menu automatically changes to the **Main Screen**. When **Unlock** is selected, you must close the **SmartKey** menu to return to the **Main Screen**.

The display automatically locks when there is no interaction for the configured time period (1-30 minutes with a default of 5 minutes).

Function	Display Locked / Active	Display Locked / Inactive	Display Unlocked / Active	Display Unlocked / Inactive
Display Touch	No	No	Yes	No
Main Screen Button	No	Yes	Yes	Yes
SmartKeys Button	Yes	No	Yes	No
Silence Button	No	No	Yes	No

## Measurement Area

The measurement area of the MX40 display is optimized to show available parameter numerics, waveforms, and alarm limits. Each element is a touch object and when you select it, further controls and menus become available.

## Measurement Area Display Configurations

The display of your MX40 is configured/can operate in one of four available orientations:

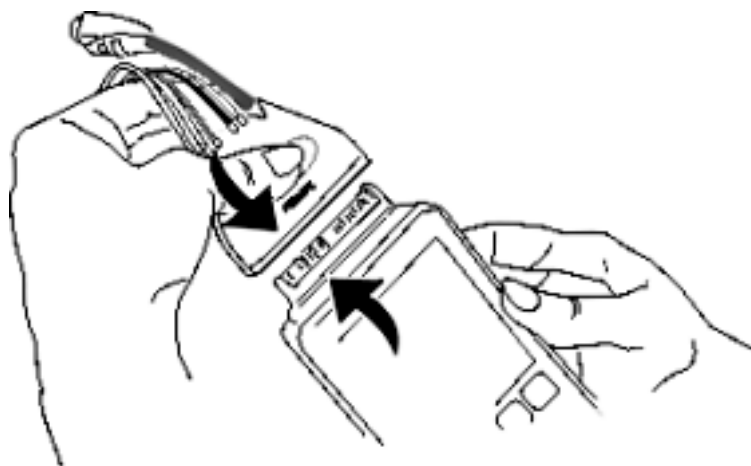
- Portrait - No Waveforms and six Numerics (IIC iX only)
- Portrait - One Waveform and four Numerics

## Operating and Navigating

- Portrait - Two Waveforms and two Numerics (IIC Release N and IIC iX only)
- Landscape - Two Waveforms and three Numerics (IIC Release N and IIC iX only)
- Portrait - Viewable Chest Diagram and two Numerics

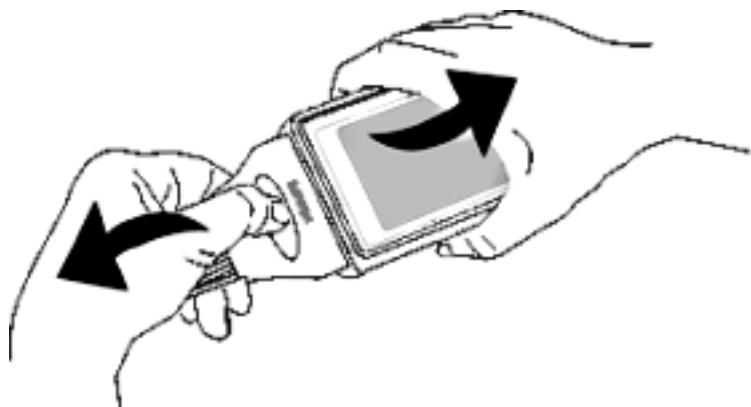
## Connecting/Disconnecting the Patient Cable

The patient cable is connected to the MX40 as shown in the illustration below.

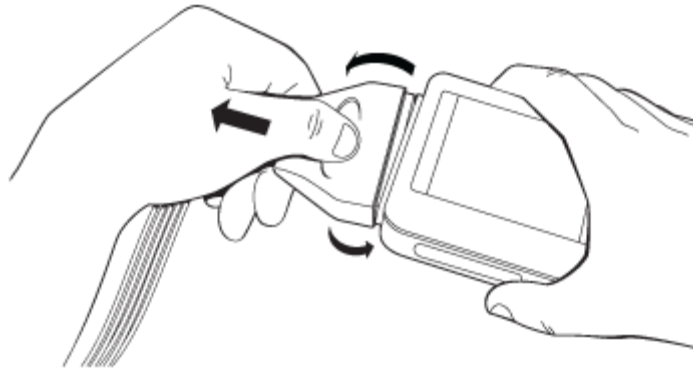


When connecting to the MX40, there is a slight clicking sound that signifies that the cable is securely connected.

Typically, the patient cable may be disconnected as shown below.



During initial use of the MX40, the secure connection between the patient cable and the device may be difficult to disconnect. Should this occur, use the alternative procedure shown below.



---

### Caution

Never disconnect the patient cable by pulling on the leadwires, as this may damage wires over time.

---

## Understanding Settings

Each aspect of how the MX40 works and looks is defined by a setting. There are a number of different categories of settings, including:

- Screen Settings - to define the selection and appearance of elements on each individual display screen.
- Measurement Settings - to define setting unique to each measurement, e.g. high and low alarm limits.
- Monitor Settings - including settings that affect more than one measurement or display screen, for example alarm volume and alarm pause time.

You must be aware that, although many settings can be changed during use, permanent changes to settings can only be done in Configuration Mode. All settings are restored to their default setting when the patient is discharged or the MX40 is powered off.

## Changing Measurement Settings

Each measurement has a setup menu in which you can adjust its settings. You enter the setup menu by selecting the measurement numeric.

## ECG Settings at the MX40

Setting	Description
Alarm Limits	Heart Rate alarm limits can be viewed locally at the MX40. Limits set at the Information Center (Release N or later or iX) are reflected at the MX40 when connected on the network.
Primary (used for arrhythmia analysis only) (Set at IIC Release N or IIC iX. View only.)	I, II, III, aVR, aVL, aVF, V1-V9, MCL, V3R, V4R, V5R. Available waveforms are based on lead set type. Lead II is the default.
Secondary (used for arrhythmia analysis only) (Set at IIC Release N or IIC iX. View only.)	I, II, III, aVR, aVL, aVF, V1-V9, MCL, V3R, V4R, V5R. Available waveforms are based on lead set type. Lead V is the default.
Paced Mode (Set at IIC Release N or IIC iX)	On, Off
Adjust Size	Set ECG gain to x1/2, x1, x2, x4
Arrhythmia	Initiate an Arrhythmia Relearn; View Arrhythmia Alarm Limits; Turn Arrhythmia Annotation On/Off.
Lead Placement	Set EASI, Standard

Setting	Description
ECG	Set ECG On/Off
New Lead Setup	When IntelliVue Patient Monitor lead sets are in use, select 3-wire, or 5-wire.
Va Lead	Shows position of Va, or C1, electrodes. Choices are V1-V9, v3R, V4R, V5R.
Vb Lead	Shows position of Vb, or C2, electrodes. Choices are V1-V9, v3R, V4R, V5R.
Change Numeric	Selects parameter numeric to display in place of current HR numeric.

## Waveform Settings at the MX40

Setting	Description
Wave 1	Primary, Secondary, I, II, III, aVR, aVL, aVF, V1-V9, MCL, V3R, V4R, V5R. Available waveforms are based on patient cable type. Lead II is the default. If Primary or Secondary are selected, then the waveform displayed is the waveform configured as primary or secondary for arrhythmia analysis.
Wave 2	Primary, Secondary, I,II, III, aVR, aVL, aVF, V1-V9, MCL, V3R, V4R, V5R, Pleth (if SpO <sub>2</sub> is available), Resp (if Resp is available). Available waveforms are based on patient cable type. Lead V is the default. If Primary or Secondary are selected, then the waveform displayed is the waveform configured as primary or secondary for arrhythmia analysis.

Primary or secondary waveform configuration changes made at the Information Center change the MX40.

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## Battery Information

### Battery Safety Information

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#### Warnings

- The battery compartment door must be closed during defibrillation.
- Use the Philips Rechargeable Lithium-ion Battery or 3 Duracell Alkaline batteries, size AA, MN 1500, 1.5V, to ensure specified performance and correct battery gauge reporting. Outdated, mismatched, or poor-quality batteries can give unacceptable performance (e.g., insufficient Battery-Low warning time). If you are using disposable batteries, the use of fresh high-quality alkaline batteries is strongly recommended.
- Certain failure conditions, such as short circuits, can cause a battery to overheat during use. High temperatures can cause burns to the patient and/or user. If the MX40 becomes hot to the touch, remove it from the patient and place it aside until it cools. Then remove the batteries and discard them. Have the MX40 checked by your service provider to identify the cause of overheating.
- If you receive a TELE BATTERY LOW, TELE BATTERY EMPTY, REPLACE BATTERY T, or TELE BATTERY TEMP alarm, the batteries must be promptly replaced. If these conditions are not corrected, they will result in a device shutdown and cessation of monitoring.
- Disposable batteries should be removed from the MX40 at the end of the battery's useful life to prevent leakage.

If battery leakage should occur, use caution in removing the battery. The leaked substance may cause eye or skin irritation. Avoid contact with skin. Clean the battery compartment according to the instructions in the Maintenance section. Wash hands.

- To eliminate the risk of electrical shock or burn, do not carry loose batteries on your person, e.g. in clothing pockets.
- 

#### Cautions

- Use of AA Lithium batteries or batteries with terminal voltage >1.6V may cause damage to the device.
  - When monitoring with the WLAN version of the MX40 (Model 865352), the lithium-ion rechargeable battery is the only approved power source. Use of AA disposable batteries is not supported.
-

## Lithium-ion Rechargeable Battery Care

Care of the rechargeable battery begins when you receive a new battery for use and continues throughout the life of the battery. The table below lists battery care activities and when they should be performed.

Activity	When to Perform
Perform a visual inspection.	Before inserting a battery in the MX40.
Charge the battery.	Upon receipt, after use, or if a low battery state is indicated. To optimize performance, a fully (or almost fully) discharged battery should be charged as soon as possible.
Clean the battery	At each patient discharge, or in cases when the battery is exposed to contaminants.
Charge stored batteries to at least 90% of their capacity every six months.	When not in use for an extended period of time.
Decommission the battery	When any of the following INOPs are displayed on the MX40: <b>TELE SERVICE BATTERY</b> <b>TELE BATTERY TEMP</b>

Rechargeable batteries are charged using the IntelliVue CL Charging Station. For information on charging station use, see Charging Li-ion Rechargeable Batteries p. 14-8 .

**Note** — The battery capacity of re-chargeable batteries degrades over time and number of recharge cycles. Toward the end of its useful life, the battery capacity may be reduced by 25-30%. If this reduced battery life is unacceptable based on your use model, Philips recommends replacing the rechargeable battery sooner.

## Lithium-ion Rechargeable Battery Handling Precautions

Lithium-ion batteries store a large amount of energy in a small package. Use caution when handling the batteries; misuse or abuse could cause bodily injury and/or equipment damage.

- Do not short circuit - take care that the terminals do not contact metal (e.g. coins) or other conductive materials during transport and storage.
- Do not crush, drop or puncture - mechanical abuse can lead to internal damage and internal short circuits that may not be visible externally.
- Do not apply reverse polarity.

## Battery Information

- Do not incinerate batteries or expose them to temperatures above 60°C (140°F).

If a battery has been dropped or banged against a hard surface, whether damage is visible externally or not:

- discontinue use.
- dispose of the battery in accordance with the disposal instructions.

### Lithium-ion Rechargeable Battery Storage

When storing rechargeable batteries, make sure that the battery terminals do not come into contact with metallic objects or other conductive materials.

If batteries are stored for an extended period of time, they should be stored in a cool, dry place, ideally at 15°C (60°F), with a state of charge of 20% to 90%. Storing batteries in a cool place slows the aging process.

The batteries should not be stored at a temperature outside the range of -20°C (-4°F) to 50°C (122°F).

Stored batteries should be should be charged to at least 90% of their capacity every 6 months. They should be charged to full capacity prior to use.

**Note** — Storing batteries at temperatures above 38°C (100°F) for extended periods of time could significantly reduce the batteries' life expectancy.

## Inserting/Removing Batteries

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### Warning

Arrhythmia relearning is initiated whenever the MX40's batteries are removed for one minute or longer. Be sure to check your patient's arrhythmia annotation for accuracy whenever relearn has occurred.

---

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### Caution

Remove the batteries before storing the MX40 for an extended period of time.

---



The battery compartment is located on the back of the MX40, accessible by opening the compartment door from the bottom. It accommodates three AA 1.5V Alkaline batteries or the Philips Rechargeable Lithium-ion battery. Only these batteries should be used.

**Note—** Lithium-ion batteries should be fully charged prior to first use.

**Important—** Do not use other rechargeable batteries. Use of this type of battery will adversely affect:

- Battery gauge performance
- Battery low warnings
- Battery life performance

## Inserting Batteries

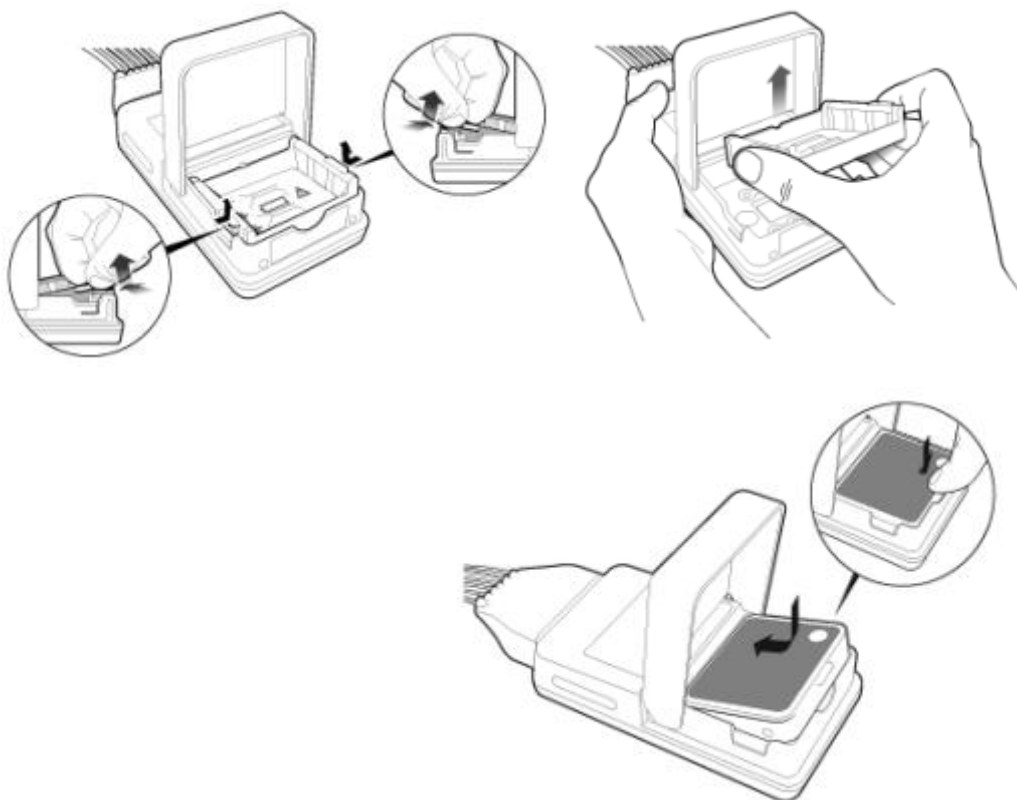
- ***Insert the rechargeable lithium-ion battery using the following procedure:***

Open the battery compartment by lifting up on both bottom sides of the compartment door.



## Battery Information

- 1 Remove the AA battery tray if present.
- 2 Insert the battery pack so that the raised tab is aligned with the cutout in the base of the battery compartment.

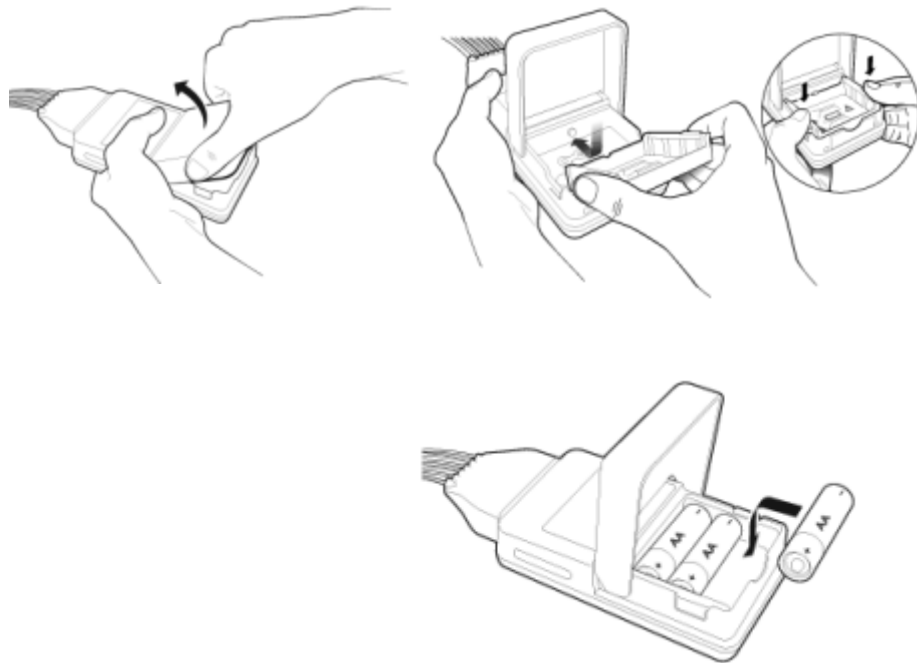


- 3 Close the battery compartment door.
- 4 Watch for the start-up screen on the front of the MX40 to illuminate briefly.

➤ ***Insert AA batteries into the MX40 using the following procedure:***

- 1 Open the battery compartment by lifting up on both bottom sides of the compartment door.
- 2 Insert the AA battery tray if not already present.
- 3 Insert three AA 1.5V Alkaline batteries, matching the polarity with the + indications inside the compartment.

**Note**—all batteries are inserted with the + polarity in the same direction. Use of AA batteries is not supported with the WLAN MX40 (Model Number 865352). Use only the rechargeable lithium-ion battery.



- 4 Close the battery compartment door.
- 5 Watch for the start-up screen on the front of the MX40 to illuminate briefly.

## **Removing the Batteries**

Batteries should be removed when the MX40 is not in use or is being stored.

To remove the batteries, open the battery compartment door and push from the opening at the bottom of the compartment to pop the batteries out. Device settings (patient cable type, SpO<sub>2</sub> mode, volume, etc.) are retained when the batteries are removed.

Do not use AA batteries that have different energy levels remaining. Fresh AA batteries are recommended for each new application.

## Battery Information

**Important—** Do not "store" disposable AA batteries by leaving them in the incorrect polarity position in the MX40.

Be careful not to short circuit the batteries. Batteries can get hot when shorted. Short circuits are caused when a piece of metal touches both the positive and negative terminals simultaneously. More than a momentary short circuit will generally reduce the battery life. In case of a short circuit, discard the batteries, or just the shorted one if the batteries are new.

### Disposal of Batteries

When disposing of batteries, follow local laws for proper disposal. Dispose of batteries in approved containers. If local regulations require you to recycle batteries, recycle batteries in accordance with those regulations.

## Battery Charge Status

The battery charge indicator displays in the Status Area and communicates the remaining battery charge time when using both AA batteries or the rechargeable lithium-ion battery.

When the MX40 is initially powered-on, it takes approximately 25 seconds for the indicator to populate. During this time, the indicator displays a ? in the battery icon.

In order to guarantee overall device performance, certain functionality is disabled when the battery charge reaches critical levels. See the tables below for additional information about battery status.

### Lithium-ion Rechargeable Battery Charge Status

Approximate Battery Life Remaining	Approximate Time Remaining (ECG only)	Approximate Time Remaining (ECG & Spo2 Continuous)	Functionality Disabled	Battery Indicator LCD Segments
100%	~ 25 hours	~ 14 hours	None	5 Green
75%	< 19 hours	< 10.5 hours	None	4 Green
50%	< 13 hours	< 7 hours	None	3 Green
25%	< 6 hours	< 3.5 hours	None	2 Green
10%	< 3 hours	< 1.5 hours	None	1 Green

Approximate Battery Life Remaining	Approximate Time Remaining (ECG only)	Approximate Time Remaining (ECG & Spo2 Continuous)	Functionality Disabled	Battery Indicator LCD Segments
Low battery level to replace/charge battery level	< 30 minutes	< 30 minutes	SpO <sub>2</sub> and short-range radio are disabled. Display is at half brightness	1 Red Red Battery Icon Audio
Replace/charge battery level	< 10 minutes	< 10 minutes	Device shutdown	1 Red Red Battery Icon

### AA Battery Charge Status

Approximate Battery Life Remaining	Approximate Time Remaining (ECG only)	Approximate Time Remaining (ECG & Spo2 Continuous)	Functionality Disabled	Battery Indicator LCD Segments
100%	~ 24 hours	~ 9 hours	None	5 Green
75%	< 18 hours	< 7 hours	None	4 Green
50%	< 12 hours	< 5 hours	None	3 Green
25%	< 6 hours	< 2 hours	None	2 Green
10%	< 2 hours	< 1 hours	None	1 Green
Low battery level to replace/charge battery level	< 30 minutes	< 30 minutes	SpO <sub>2</sub> and short-range radio are disabled. Display is at half brightness.	1 Red Red Battery Icon Audio
Replace/charge battery level	< 10 minutes	< 10 minutes	Device shutdown	1 Red Red Battery Icon

## Pouch Use

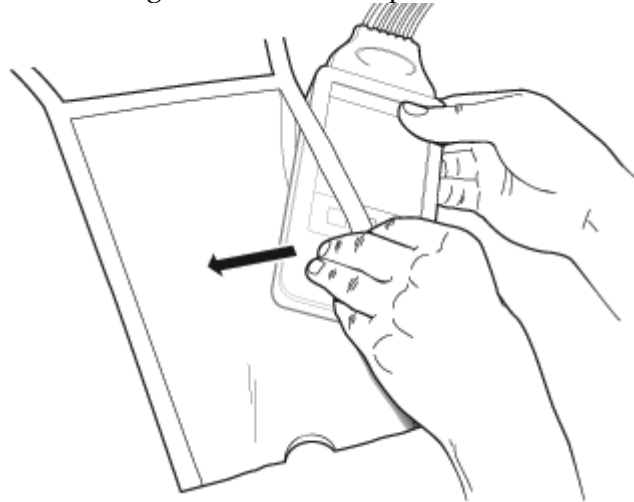
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### Pouch Use

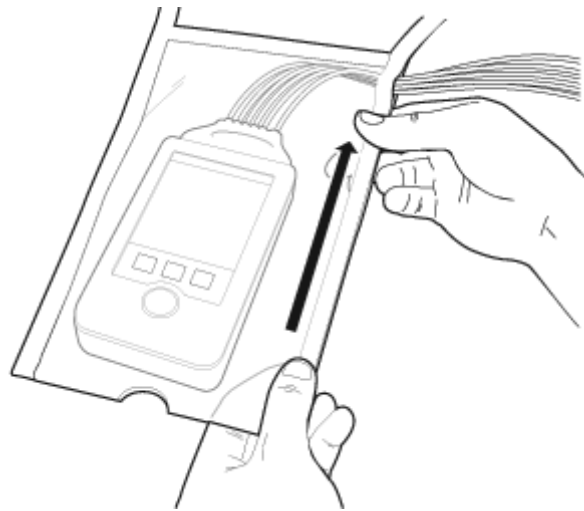
The MX40 is not intended for direct contact with the patient's skin. During normal use, the MX40 should be worn over clothing, in a pocket or, preferably, in a pouch. The Waterproof Carry Pouch with clear front is an appropriate means for holding the MX40. See Appendix A, "Accessories" for ordering information.

### Securing the Pouch

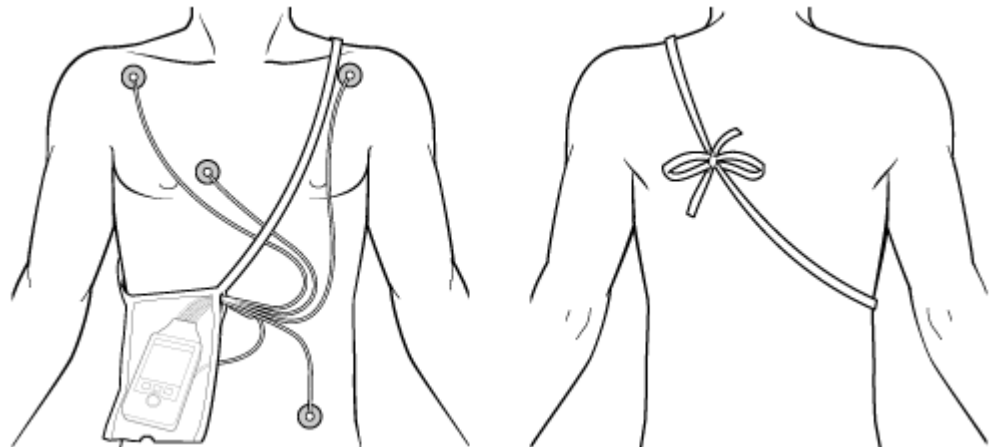
- 1 See the *Carry Pouch, Waterproof, Instructions for Use*, P/N 453564267571, for more information.
- 2 Insert the MX40 into the pouch with lead wires and SpO<sub>2</sub> sensor cable, if used, exiting from the side opening of the pouch. Pinch the velcro enclosures together to close the pouch around the cables.



- 3 Seal the pouch.



- 4 Secure the pouch on the patient with the ties around the patient's shoulder and under the arm.



- 5 Check that the patient is comfortable wearing the pouch with the MX40.

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### Cautions

- The pouch is designed to be used exclusively with the MX40. It is not intended to be used to store patient's personal devices, e.g. cell phones.
  - Philips recommends that when using a pouch to attach the MX40 to your patient, consider your patient's condition and be careful about placement of the straps, as the straps could present a strangulation hazard.
-

## Showering

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### Warning

When the patient is showering, signal quality and leads off detection may be compromised due to significant movement. Appropriate clinical precautions must be taken.

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### Caution

Because the touchscreen display is sensitive to water impact, the display should be locked when showering.

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The MX40 can be used to monitor a patient in the shower, but only when placed inside a Philips carrying pouch and secured on the patient as described above. The combination of the MX40 and pouch will withstand showering for up to 10 minutes.

### Drying the MX40 after Showering

After showering, perform the following steps to continue monitoring:

- 1 Remove the battery.
- 2 Pat dry the patient cable connections at the electrodes.
- 3 Wipe the lead wires with care.
- 4 If wet, dry the outside of the MX40 with a non-lint producing cloth.
- 5 If wet, wipe dry the inside of the battery compartment. Dry the batteries.
- 6 If wet, disconnect the patient cable and shake out any water. Dry the connector pin area with a cotton swab.
- 7 Re-insert the battery.

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### Caution

The MX40 should not be used for monitoring if the battery compartment is wet. Remove the batteries and wipe the compartment dry before continued monitoring use.

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### **Accidental Liquid Exposure**

If the MX40 is accidentally immersed in liquid, no damage to the device and no electrical safety issues for the patient will result. Remove the device, dry it off, and follow the procedure for cleaning/sterilization under "Cleaning and Sterilization" as needed.

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## Telemetry Mode Use

To minimize patient disruption, the MX40 operates in Telemetry Mode when connected to the Information Center. In Telemetry Mode, the local volume is set to zero and the display is off. You can activate the display at any time by touching the Main Screen button for two seconds. All active alarms can be viewed when the display is on, however audible alarm indicators are not annunciated. Regardless of the display status, all measurement data is being sent to the Information Center. Telemetry Mode is only available when connected to the Information Center.

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## Monitoring Mode Use

You may find the use of Monitoring Mode helpful when spending extended time directly with your patient, e.g. during transport, showering, dressing change. The display is always on for easy viewing and should an alarm condition occur, it will be announced locally at the MX40 and at the Information Center if networked connected. If the MX40 is not network connected, the alarm is only announced locally.

➤ ***To use Monitor Mode:***

- 1 Press the SmartKeys Button.
- 2 Press the **Mode: Telemetry / Mode: Monitor** SmartKey and choose **Mode: Monitor**.

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## Briefing the Patient

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### Warning

Patients should be instructed not to interact with the display of the device and to not open the battery compartment while the MX40 is in use.

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**Note** — Pausing alarms at the Information Center activates the MX40 display. Patients should be notified that this is normal operation and not cause for any concern.

If the Multi-Function button has been configured to generate a Nurse Call alarm, recording at the Information Center, or both, instruct the patient to use the button when needed.

If desired, you can turn off patient use of the Multi-Function button at the Information Center. For more information see Patient Configurable Settings in Telemetry Setup p. 11-10.

## 5. Alarms

The section provides alarm information that applies to all measurements. Measurement-specific alarm information is discussed in the sections on individual measurements.

Alarms Overview .....	5-2
Physiologic Alarms .....	5-10
Technical Alarms (INOPs) .....	5-14

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## Alarms Overview

The MX40 has two different types of alarms: physiological alarms and INOPs. For MX40 devices operating with IntelliVue Information Center Release L and M, physiological alarms are not available locally on the MX40. INOPs are displayed as described here.

For MX40 devices operating with IntelliVue Information Center Release N or IntelliVue Information Center iX, physiological alarms are available locally on the MX40 regardless of network connection to the Information Center. Alarm settings are as configured by the Information Center. Changes to physiological alarm settings can only be made at the Information Center. Audible alarm indicators are annunciated only when operating in Monitor Mode or when the MX40 is not networked connected.

### Physiological Alarms

Physiological alarms are red and yellow alarms. A red alarm indicates a high priority patient alarm such as a potentially life threatening situation (for example, asystole). A yellow alarm indicates a lower priority patient alarm (for example, a low SpO<sub>2</sub> alarm limit violation). Additionally there are short yellow alarms, most of which are specific to arrhythmia-related patient conditions (for example, ventricular bigeminy).

### INOPs

INOPs are technical alarms, they indicate that the monitor cannot measure or detect alarm conditions reliably. If an INOP interrupts monitoring and alarm detection (for example, LEADS OFF), the monitor places a question mark in place of the measurement numeric and an audible indicator tone will be sounded. INOPs without this audible indicator indicate that there may be a problem with the reliability of the data, but that monitoring is not interrupted.

Most INOPs are light blue, however there are a small number of INOPs which are always yellow or red to indicate a severity corresponding to red and yellow alarms. The following INOPs can also be configured as red or yellow INOPs to provide a severity indication:

- ECG LEADS OFF
- REPLACE BATTERY (when using disposable batteries)
- TELE BATT EMPTY (when using the rechargeable battery pack)

All monitors in a unit should have the same severity configured for these INOPs.

The MX40 is designed to achieve visual alarm notification at a distance of up to one meter, which is consistent with its intended use model as a wearable monitor.

Alarms are indicated after the alarm delay time. This is made up of the system delay time plus the trigger delay time for the individual measurement. For more information see ECG Performance Disclosure/Specifications p. 15-27 .

A downward facing arrow symbol next to the alarm message informs you that more than one message is active and the messages rotate every three seconds. The monitor sounds an audible indicator for the highest priority alarm.

## Visual Alarm Indicators

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### Warning

The MX40 display is inactive for a majority of the time because it is operating in Telemetry Mode. You must activate the screen to view or hear any alarms at the MX40. Upon activating the screen, the alarm volume may be set to zero if desired.

---

### Alarm Message

An alarm message text appears in the alarm status area at the top of the screen indicating the source of the alarm. The background color of the alarm message matches the alarm priority: red for red alarms, yellow for yellow alarms, light blue for standard INOPs, red for red INOPs and yellow for yellow INOPs. The asterisk symbols (\*) beside the alarm message match the alarm priority: \*\*\* for red alarms, \*\* for yellow alarms, \* for short yellow alarms. Standard INOPs do not have a symbol, red and yellow INOPs have exclamation marks beside the alarm message: !!! for red INOPs and !! for yellow INOPs. If more than one alarm is present, there is a downward facing arrow symbol at the right side and the active alarm/inop messages rotate every three seconds.

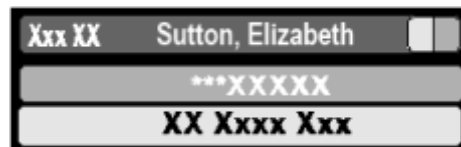
Alarm limit violation messages are displayed in text form, for example **\*\* SpO<sub>2</sub> LOW.**

## Alarms Overview

**Alarm Indicator**

An Alarm Indicator on the MX40 main display communicates alarm/INOP conditions that have not been acknowledged. The alarm indicator is divided into two sections and appears in the upper right hand corner normally occupied by the time display. The right section flashes for a physiological alarm, except for short yellow alarms where the indicator will light for approximately six seconds. The color is yellow or red corresponding to the highest priority alarm currently present.

An unacknowledged physiological alarm and INOP appears as (portrait view):



An acknowledged physiological alarm and INOP with an additional unacknowledged physiological alarm appears as (landscape view):



The left section lights continuously for a standard INOP and flashes for INOPs configured as red or yellow alarms as follows:

INOP Color	On	Off
Yellow	1.0 seconds	1.0 seconds
Red	0.25 seconds	0.25 seconds

If only physiological alarms are present, and no INOPs, the physiological alarms will use both left and right sections to flash (for red and yellow alarms) or light for approximately six seconds (for short yellow alarms). If only INOPs are present, and no physiological alarms, red and yellow INOPs will use both left and right sections to flash, but standard INOPs will always light continuously in the left section only.

Once all alarm/INOP conditions are acknowledged, the time display reappears.

**Flashing Numeric**

The numeric of the measurement in alarm flashes.



## Audible Alarm Indicators when in Monitoring Mode

The audible alarm indicators configured for your monitor depend on which alarm standard applies in your hospital. Audible alarm indicator patterns are repeated until you acknowledge the alarm by switching it off or pausing it, or until the alarm condition ceases (if audible alarm indication is set to non-latching).

---

### Warning

- Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in patient danger. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.
  - No audible alarm indicators are available when the MX40's volume setting is zero or when operating in Telemetry Mode. Audible alarm indicators become active as soon as the MX40 is no longer connected to the Information Center.
- 

### Traditional Audible Alarms (HP/Agilent/Philips/Carenet)

- Red alarms and red INOPs: A high pitched sound is repeated once a second.
- Two-star yellow alarms and yellow INOPs: A lower pitched sound is repeated every two seconds.
- One-star yellow alarms (short yellow alarms): The audible indicator is the same as for yellow alarms, but of shorter duration.
- Standard INOPs: an INOP tone is repeated every two seconds.

### ISO/IEC Standard Audible Alarms

- Red alarms and red INOPs: A high pitched tone is repeated five times, followed by a pause.
- Two-star yellow alarms and yellow INOPs: A lower pitched tone is repeated three times, followed by a pause.
- One-star yellow alarms (short yellow alarms): The audible indicator is the same as for yellow alarms, but of shorter duration.
- Standard INOPs: a lower pitched tone is repeated twice, followed by a pause.

## Acknowledging Alarms

To acknowledge all active physiological alarms and INOPs, touch the Silence Alarm button. This switches off the audible alarm indicators, if present, and alarm messages at the MX40 and at the IntelliVue Information Center iX.

A check mark beside the alarm message indicates that the alarm has been acknowledged .

If the condition that triggered the alarm is still present after the alarm has been acknowledged, the alarm message stays on the screen with a check mark symbol beside it, except for NBP alarms and alarms from other intermittent measurements. When such an alarm is acknowledged the alarm message disappears.

If the alarm condition is no longer present, all alarm indicators stop and the alarm is reset.

Switching off the alarms for the measurement in alarm, or switching off the measurement itself, also stops alarm indication.

## Pausing or Switching Off Alarms

If you want to temporarily prevent alarms from sounding, for example while you are moving a patient, you can pause alarms, if configured. Depending on your MX40 configuration, alarms are paused for one, two or three minutes.

---

### Cautions

- When operating with Information Center Release L or M, the alarm pause time of the MX40 is not configurable. The alarm pause time for the MX40 is always two minutes.
  - When operating with Information Center Release L or M, if alarms are paused at the Information Center, the "Alarms Paused" message is only displayed at the Information Center.
- 

### To Pause All Alarms

Select the **Alarms** SmartKey and select **Pause Alarms**. A timer on the display shows the remaining pause time.

## While Alarms are Paused

- In the alarm field, the MX40 displays the message ALARMS PAUSED 1:28 or ALARMS OFF, together with the alarms paused symbol or the alarms off symbol.
- No alarms are sounded and no alarm messages are shown.
- INOP messages are shown but no INOP tones are sounded.  
The only exceptions are the INOPs CUFF NOT DEFLATED, NBP CUFF OVERPRESS and INOPs relating to empty, missing and malfunctioning batteries.  
These INOPs switch the alarms on, and the INOP tones are sounded, even if alarms are paused or off. You need to remove the INOP condition first before you can switch the alarm tones off again.

---

### Warning

If connection to the Information Center is lost during an alarms paused period, upon reconnection, alarms remain paused at the Information Center for the set time. You can resume alarms from the Patient Window at the Information Center at any time.

---

## Restarting Paused Alarms

To manually switch on alarm indication again after a pause, select **Pause Alarms**.

## Alarm Limits

The alarm limits you set determine the conditions that trigger yellow and red limit alarms. For some measurements (for example, SpO<sub>2</sub>), where setting the high alarm limit to the maximum of 100 switches the high alarm off, or setting the low alarm limit to the minimum of 0 switches it off. In these cases, the alarms off symbol is not displayed.

---

### Warning

Be aware that the monitors in your care area may each have different alarm settings, to suit different patients. Always check that the alarm settings are appropriate for your patient before you start monitoring.

---

## Viewing Individual Alarm Limits

You can see the alarm limits set for each measurement next to the measurement numeric on the main screen.



## Reviewing Alarms

You can see which alarms and INOPs are currently active in the respective alarms and INOPs fields at the top of the screen.

To see the currently active alarms and INOPs listed in one place, touch the Alarms area.

All alarms and INOPs are erased from the Alarm Messages window when you discharge a patient, or if you change to Demonstration Mode.

## Review Alarms Window

The Review Alarms window contains a list of the 50 most recent alarms and INOPs with date and time information.

The Review Alarms window also shows when alarms are paused or silenced.

**Note** — Alarms that occur during an alarm suspend period will appear in the Review Alarm window, however, they are not communicated to the Information Center.

## Alarm Reminders

The MX40 provides alarm reminders when operating with IIC Release N or IIC iX. The reminder time period is selected at the Information Center.

For Information Center Release L/M, reminders are only available for INOPs.

## Latching Alarms

The alarm latching setting for your MX40 defines how the alarm indicators behave when you do not acknowledge them. When alarms are set to non-latching, their indicators end when the alarm condition ends. Switching alarm latching on means that visual and/or audible alarm indications are still displayed or announced by the monitor after the alarm condition ends. The indication lasts until you acknowledge the alarm by touching the Alarm Silence button.

## Alarm Latching Behavior

Red & Yellow Measurement Alarms		Non-latching Alarms	Visual and Audible Latching
Alarm has not been acknowledged.	Alarm condition still present.	Alarm tone on. Alarm message. Flashing numerics.	Alarm tone on. Alarm message. Flashing numerics.
	Alarm condition no longer present.	All audible and visual alarm indicators automatically stop.	Alarm tone on. Alarm message . Flashing numerics.
Alarm has been acknowledged.	Alarm condition still present.	Alarm tone off. Alarm message with check mark. Flashing numerics. Audible alarm reminder (if configured)	Alarm tone off. Alarm message with check mark. Flashing numerics. Audible alarm reminder (if configured)
	Alarm condition no longer present.	Audible and visual alarm indicators automatically stop.	Audible and visual alarm indicators automatically stop.

## Alarm Behavior at Power On

If the MX40 is powered off for longer than one minute and then powered on again (or after a loss of power lasting longer than one minute, or when a patient is discharged), the device restores the latest alarm settings from the Information Center.

If battery power is lost for less than one minute, the alarm on/off condition prior to the power loss is restored.

## Physiologic Alarms

Physiologic alarms indicate a life-threatening situation or a less urgent situation such as heart rate beyond limits.

### Warning

- Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level during patient monitoring may result in patient danger. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.

Arrhythmia alarm chaining and customizing arrhythmia alarm settings are described in the ECG and Arrhythmia Monitoring chapter. There are two levels of arrhythmia analysis available: Basic and Enhanced. Enhanced analysis includes Basic alarms.

The MX40 provides physiological alarms based on the settings at the Information Center Release N or IntelliVue Information Center iX. Alarming is not active on the MX40 until it is configured via an active association with the Information Center.

In the following table, Red (\*\*\*) alarms are listed alphabetically, followed by the Yellow (\*\*) alarms, and the Yellow (\*) alarms.

**Note** — The physiological alarm messages displayed on the MX40 use a short text format. Alarm messages displayed at the Information Center use and extended text format, e.g. "\*HR yyy<xxx".

Alarm Text	Priority	Condition	Source
*** APNEA <b>Note</b> — Only available with IIC iX.	Red	Respiration has stopped for longer than the preset apnea time.	RESP
*** ASYSTOLE	Red	Asystole. No QRS for 4 consecutive seconds	ST/AR Basic & Enhanced Arrhythmia
*** EXTREME BRADY	Red	Extreme Bradycardia. Heart Rate (yyy) less than Extreme Brady limit (xxx)	ST/AR Basic & Enhanced Arrhythmia

Alarm Text	Priority	Condition	Source
*** DESAT	Red	Very Low SpO <sub>2</sub> Saturation. SpO <sub>2</sub> value below Desaturation limit <b>Note</b> — Desat limit is set 10 points below low limit with IIC Release N. It is configurable with IIC iX.	SpO <sub>2</sub>
***EXTREME TACHY	Red	Extreme Tachycardia. Heart Rate (yyy) greater than Extreme Tachy limit	ST/AR Basic & Enhanced Arrhythmia
*** VENT FIB/TACH	Red	Ventricular Fibrillation. Fibrillatory wave (sinusoidal wave between 2-10 Hz) for 4 consecutive seconds	ST/AR Basic & Enhanced Arrhythmia
*** V-TACH	Red	Ventricular Tachycardia. Consecutive PVCs greater than or equal to V-Tach Run limit and Heart Rate greater than V-Tach limit (xxx)	ST/AR Basic & Enhanced Arrhythmia
** dQTc	Yellow	dQTc value has exceeded the dQTc high limit for > 5 minutes for 2 consecutive time periods.	ECG/QT
** MULTI ST	Yellow	Two contiguous ST leads have values exceeding elevation or depression alarm limits for > 60 sec.	ECG/ST
** NBP High	Yellow	High limit has been exceeded for high pressure limit.	NBP
** NBP Low	Yellow	Low limit has been exceeded for low pressure limit.	NBP
** QTc High	Yellow	QTc value has exceeded the QTc high limit for > 5 minute for 2 consecutive time periods.	ECG/QT
** RR HIGH <b>Note</b> — Only available with IIC iX.	Yellow	The respiration rate has exceeded the high alarm limit.	RESP
** RR LOW <b>Note</b> — Only available with IIC iX.	Yellow	The respiration rate has dropped below the low alarm limit.	RESP
**SpO <sub>2</sub> T HIGH	Yellow	High SpO <sub>2</sub> . SpO <sub>2</sub> value (yyy) greater than high SpO <sub>2</sub> limit (xxx)	SpO <sub>2</sub>
** SpO <sub>2</sub> T LOW	Yellow	Low SpO <sub>2</sub> . SpO <sub>2</sub> value (yyy) less than low SpO <sub>2</sub> limit (xxx).	SpO <sub>2</sub>
** ST-LEAD HIGH	Yellow	ST segment is elevated.	ECG/ST
** ST-LEAD LOW	Yellow	ST segment is depressed.	ECG/ST

## Physiologic Alarms

Alarm Text	Priority	Condition	Source
** ST ELEV	Yellow	Two contiguous leads have ST values exceeding the STEMI limits.	ECG/ST
*/** AFIB	Yellow	Atrial fibrillation waveform detected.	ST/AR Enhanced Arrhythmia
*/** HR High	Yellow	Heart Rate (yyy) greater than the upper Heart rate limit (xxx).	ST/AR Basic & Enhanced Arrhythmia
*/** HR Low	Yellow	Heart Rate (yyy) lower than the lower Heart Rate limit (xxx).	ST/AR Basic & Enhanced Arrhythmia
*/** IRREGULAR HR	Yellow	Consistently irregular rhythm (irregular R-R intervals).	ST/AR Enhanced Arrhythmia
* MISSED BEAT	Yellow	No beat detected for 1.75 x average R-R interval for Heart Rate greater than 120, or no beat for 1 second with Heart Rate greater than 120 (non-paced patient only).	ST/AR Enhanced Arrhythmia
* MULTIFORM PVCs	Yellow	The occurrence of two differently shaped Vs, each occurring at least twice within the last 300 beats as well as each occurring at least once within the last 60 beats.	ST/AR Enhanced Arrhythmia
* NON-SUSTAIN VT	Yellow	A run of Vs having a ventricular Heart Rate greater than V-Tach limit but lasting for less than the V-Tach Run limit.	ST/AR Enhanced Arrhythmia
*Nurse Call	Yellow	The patient has pressed the Multi-Function Button on the MX40.	
* PACER NOT CAPTURE	Yellow	No QRS for 1.75 x the average R-R interval with Pace Pulse (paced patient only).	ST/AR Basic & Enhanced Arrhythmia
* PACER NOT PACING	Yellow	No QRS and Pace Pulse for 1.75 x the average R-R interval (paced patient only).	ST/AR Basic & Enhanced Arrhythmia
* PAIR PVCs	Yellow	Two consecutive PVCs between non-PVCs.	ST/AR Enhanced Arrhythmia
* PAUSE	Yellow	No QRS detected for x seconds. Choices of >1.5 to 2.5 seconds.	ST/AR Enhanced Arrhythmia



Alarm Text	Priority	Condition	Source
* PVCs /MIN HIGH	Yellow	PVCs within one minute exceed by the PVCs/min limit (xxx).	ST/AR Basic & Enhanced Arrhythmia
* R-ON-T PVCs	Yellow	For Heart Rate less than 100, a PVC with R-R interval less than 1/3 the average interval followed by a compensatory pause of 1.25 x average R-R interval, or 2 such Vs without a compensatory pause occurring within 5 minutes of each other. (When Heart Rate is greater than 100, 1/3 R-R interval is too short for detection.)	ST/AR Enhanced Arrhythmia
* RUN PVCs	Yellow	Run of PVCs greater than or equal to 2.	ST/AR Enhanced Arrhythmia
* SVT	Yellow	Run of SVPBs greater than or equal to SVT Run limit and with SVT Heart Rate greater than the SVT Heart Rate limit.	ST/AR Enhanced Arrhythmia
* VENT BIGEMINY	Yellow	A dominant rhythm of N, V, N, V (where N= supraventricular beat, V=ventricular beat).	ST/AR Enhanced Arrhythmia
* VENT RHYTHM	Yellow	A dominant rhythm of adjacent Vs greater than Vent Rhythm limit and ventricular Heart Rate less than V-Tach limit.	ST/AR Enhanced Arrhythmia
* VENT TRIGEMINY	Yellow	A dominant rhythm of N, N, V, N, N, V (where N=supraventricular beat, V=ventricular beat).	ST/AR Enhanced Arrhythmia

## Technical Alarms (INOPs)

Technical Alarms, or INOPs (inoperative conditions), are sourced at the MX40, the ST/AR algorithm running at the Information Center, or the IntelliVue Patient Monitor. They identify inoperative conditions (that is conditions where the system is not operating properly and therefore cannot measure or detect alarm conditions reliably). There are four levels of Technical Alarms:

- **Severe** - Monitoring and alarm generation are disabled. Visual alarm indicator on the MX40. Audible tone at the Information Center. Must be acknowledged by a clinician.
- **Hard** - Monitoring and alarm generation are disabled. Visual alarm indicator on the MX40. Audible tone at the Information Center. If the hard INOP is "latched", the sound will be silenced, but the message will remain on the display until resolution of the offending condition.
- **Soft** - Monitoring and alarms remain active. Visual alarm indicator on the MX40 and at the Information Center. No audible tones are generated at the Information Center
- **Red/Yellow** - Replace Battery and ECG Leads Off INOPs may be configured to display as either Red or Yellow Technical Alarms.  
**Note** - The ECG Leads Off INOP will initially display as a cyan technical alarm until a valid ECG signal is obtained.

In the following table, technical alarms are listed alphabetically.

Alarm Text	Priority	Condition	What to do
BATTERY LOW T  Source - MX40	Soft	<ul style="list-style-type: none"> <li>• There is less than 15 minutes of monitoring time remaining (AA batteries).</li> <li>• Lithium-ion battery level is <math>\leq 10\%</math> or has <math>\leq 30</math> minutes remaining time.</li> </ul>	<ul style="list-style-type: none"> <li>• Replace batteries promptly to avoid shutdown and cessation of monitoring.</li> <li>• Insert a charged lithium-ion battery pack.</li> </ul>
CANNOT ANALYZE ECG  Source - MX40 (IIC iX only) and Information Center	Hard	Arrhythmia algorithm cannot reliably analyze the ECG data on any monitored leads.	Assess the lead selections, initiate relearn, and validate analyzed rhythm. Check other INOPs for possible source of problem.

Alarm Text	Priority	Condition	What to do
CHECK PAIRING  <b>Source - MX40</b>	Yellow Technical Alarm	<ul style="list-style-type: none"> <li>There is a problem with device pairing.</li> <li>When the MX40 is wirelessly paired with an X2 patient monitor (no label) docked with a larger networked MP series monitor, and the network connection is lost.</li> </ul>	<ul style="list-style-type: none"> <li>Check that the bedside monitor or cableless measurement device is correctly paired.</li> <li>Select the correct device to be paired.</li> </ul>
cl NBP Batt Low  <b>Source - Cableless Measurement Device</b>	Hard	CL NBP Pod weak battery condition.	Charge CL NBP Pod.
cl NBP Batt Empty  <b>Source - Cableless Measurement Device</b>	Severe	CL NBP Pod empty battery condition. Monitoring is not possible.	<ul style="list-style-type: none"> <li>Replace CL NBP Pod.</li> <li>Recharge depleted CL NBP Pod.</li> </ul>
cl NBP DISCONNECT  <b>Source - Cableless Measurement Device</b>	Hard	CL NBP Pod is not connected with the MX40.	<ul style="list-style-type: none"> <li>Resolve interference condition.</li> <li>Reduce range between CL NBP Pod and MX40.</li> </ul>
cl SpO <sub>2</sub> Batt Low  <b>Source - Cableless Measurement Device</b>	Hard	CL SpO <sub>2</sub> Pod weak battery condition.	Charge CL SpO <sub>2</sub> Pod.
cl SpO <sub>2</sub> Batt Empty  <b>Source - Cableless Measurement Device</b>	Severe	CL SpO <sub>2</sub> Pod empty battery condition. Monitoring is not possible.	<ul style="list-style-type: none"> <li>Replace CL SpO<sub>2</sub> Pod.</li> <li>Recharge depleted SpO<sub>2</sub> Pod.</li> </ul>
cl SpO <sub>2</sub> DISCONNECT  <b>Source - Cableless Measurement Device</b>	Hard	CL SpO <sub>2</sub> Pod is not connected with the MX40.	<ul style="list-style-type: none"> <li>Resolve interference condition.</li> <li>Reduce range between CL SpO<sub>2</sub> Pod and MX40.</li> </ul>
!!!! CUFF NOT DEFLATED  <b>Source - Cableless Measurement Device</b>	Severe	Cuff pressure has exceeded the specified safety limit.	Remove cuff and tubing and expel air.
!!!! CUFF OVERPRESS  <b>Source - Cableless Measurement Device</b>	Severe	Cuff pressure has increased above overpressure safety limits.	Remove cuff and tubing and expel air.

## Technical Alarms (INOPs)

Alarm Text	Priority	Condition	What to do
ECG/ARRH ALARM(S) OFF  <b>Source - MX40</b>	Soft	ECG is turned off.	Turn on ECG.
ECG LEADS OFF Note This INOP may also be configured to display as a Red or Yellow Technical Alarm.  <b>Source - MX40</b>	Red or Yellow or Hard Technical Alarm	<ul style="list-style-type: none"> <li>Multiple leads are off.</li> </ul>	Re-attach ECG leads to patient..
<electrode> LEAD OFF  <b>Source - MX40</b>	Hard	Single lead is off. If primary lead is MCL, lead will be identified as V/C in INOP text.	Re-attach ECG leads to patient.
LEADSET UNPLUGGED  <b>Source - MX40</b>	Hard	<ul style="list-style-type: none"> <li>Patient cable has been unplugged from the MX40.</li> <li>Incompatible leadset attached to patient cable.</li> </ul>	<ul style="list-style-type: none"> <li>Re-attach the patient cable.</li> <li>Replace the leadset.</li> </ul>
LEADSET LIFE	Soft	The single-patient use leadset has exceeded its limit of 25 cycles.	Replace with new leadset.
LOCAL AUDIO OFF  <b>Source - MX40</b> <b>Note</b> — This is normal operation in Telemetry Mode.	Soft	There is no alarm audio notification when operating in Telemetry Mode.	Change to Monitor Mode.
NBP INTERRUPTED  <b>Source - Cableless Measurement Device</b>	Hard	The preset maximum time for the total measurement has been exceeded.	Reduce patient movement and avoid interaction with the cuff and tubing.
NBP MEASURE FAILED  <b>Source - Cableless Measurement Device</b>	Hard	Measurement values cannot be derived.	<ul style="list-style-type: none"> <li>Attach cuff to new location on patient.</li> <li>Replace cuff.</li> </ul>

Alarm Text	Priority	Condition	What to do
NBP EQUIP MALF  <b>Source - Cableless Measurement Device</b>	Hard	<ul style="list-style-type: none"> <li>• Tubing may be obstructed or kinked.</li> <li>• Hardware malfunction.</li> </ul>	<ul style="list-style-type: none"> <li>• Check tubing.</li> <li>• If condition persists, contact Service.</li> </ul>
NO ALARM DISPLAY  <b>Source - MX40</b>	Soft	When operating with Information Center Release L Or M, there is no local alarming at the MX40, networked or non-networked.	Condition is not present when operating with Information Center Release N or later (unless specifically configured to operate in this way).
NO CENTRAL MONITOR (appears at MX40 only)  <b>Source - MX40</b>	Hard	<ul style="list-style-type: none"> <li>• The MX40 is out of range of the network.</li> <li>• Patient Sector at the Information Center is in Standby.</li> </ul>	<ul style="list-style-type: none"> <li>• Return the MX40 to the coverage area.</li> <li>• Select Resume at the Information Center.</li> </ul>
NO HOST MONITOR  <b>Source - MX40</b>	Hard	The paired MX40/bedside monitor is out of short-range radio range or there is excessive radio interference.	<ul style="list-style-type: none"> <li>• Reduce the distance between the devices.</li> <li>• Identify and remove interference source.</li> </ul>
NO SIGNAL (appears at the Information Center only)  <b>Note</b> — When operating with IIC iX, the INOP will display as NO DATA PWM. <b>Source - Information Center</b>	Hard, Latched	<ul style="list-style-type: none"> <li>• The MX40 is outside the coverage area, or</li> <li>• No batteries in the MX40, or</li> <li>• The MX40 has failed.</li> </ul>	<ul style="list-style-type: none"> <li>• Make sure that the MX40 is within the coverage area and has good batteries.</li> <li>• Replace the MX40 if Power On Self Test fails.</li> <li>• Put bed in Standby.</li> <li>• Contact Service</li> </ul>
REPLACE BATTERY T  <b>Source - MX40</b> <b>Note</b> — This INOP may also be configured to display as a Red or Yellow Technical Alarm.	Red or Yellow or Hard Technical Alarm, Latched	Dead battery. No monitoring is occurring.	Replace batteries.
RESP EQUIP MALF  <b>Source - MX40</b>	Hard	<ul style="list-style-type: none"> <li>• Malfunction in the Resp equipment.</li> <li>• MX40 requires calibration.</li> </ul>	Contact Service.
RESP LEAD OFF  <b>Note</b> — OR leadsets cannot be used to monitor Resp with the MX40. <b>Source - MX40</b>	Hard	Resp lead off.	Re-attach lead to patient.

## Technical Alarms (INOPs)

Alarm Text	Priority	Condition	What to do
SOME ECG ALARMS OFF	Soft	Some ECG alarms have been turned off at the Information Center.	For information only.
SpO <sub>2</sub> T EQUIP MALF  <b>Source - MX40</b>	Hard	Malfunction in the SpO <sub>2</sub> equipment	Contact Service.
SpO <sub>2</sub> T ERRATIC  <b>Source - MX40</b>	Hard	Erratic SpO <sub>2</sub> measurements, often due to a faulty sensor or invalid SpO <sub>2</sub> measurements, or incorrect transducer position	Repeat measurement, reposition sensor on patient, or finally, replace sensor.
SpO <sub>2</sub> T EXTD UPDATE Numeric is replaced by a -?-.  <b>Source - MX40</b>	Soft	The update period of displayed values is extended due to an NBP measurement on the same limb or an excessively noisy signal.	If NBP is not active, check the sensor placement. Reposition the sensor on patient, or replace sensor.
SpO <sub>2</sub> T LOW PERF  <b>Source - Monitor</b>	Soft	Accuracy may be reduced due to low perfusion. Data displayed with ?.	Increase perfusion. Change sensor site. Avoid site distal to BP cuff or intra-arterial line. Warm the site.
SpO <sub>2</sub> T INTERFERENCE  <b>Source - MX40</b>	Hard	Level of ambient light or level of electrical interference are so high that the SpO <sub>2</sub> sensor cannot measure SpO <sub>2</sub> and pulse rate.	Reduce ambient light to sensor or electrical noise sources.
SpO <sub>2</sub> T NO SENSOR  <b>Note</b> — Silencing this technical alarm turns off the SpO <sub>2</sub> measurement on the MX40 and at the Information Center. <b>Source - MX40</b>	Hard	No sensor attached to SpO <sub>2</sub> device.	Attach SpO <sub>2</sub> sensor.
%SpO <sub>2</sub> T NOISY SIGN  <b>Source - MX40</b>	Hard	Excessive patient movements or electrical interference are causing irregular pulse patterns	Reduce movement or electrical noise sources.
SpO <sub>2</sub> T NO PULSE  <b>Source - MX40</b> <b>Note</b> — When paired directly with an IntelliVue MP5 Patient Monitor, the INOP will display as SpO <sub>2</sub> T SENSOR OFF.	Hard	<ul style="list-style-type: none"> <li>Pulse is too weak or not detectable</li> <li>Sensor has fallen off at patient.</li> </ul>	<ul style="list-style-type: none"> <li>Check connection to patient.</li> <li>Change sensor site. Avoid site distal to BP cuff or intra-arterial line.</li> </ul>

Alarm Text	Priority	Condition	What to do
SpO <sub>2</sub> POOR SIGNAL <b>Source - MX40</b>	Soft	Although a measurement may be possible, its accuracy may be reduced due to poor signal quality.	<ul style="list-style-type: none"> <li>• Apply the sensor according to the manufacturer's instructions.</li> <li>• Relocate the sensor to a different site on the patient.</li> </ul>
SpO <sub>2</sub> T SEARCHING <b>Source - MX40</b>	Soft	The patient signal is analyzed, but a valid numeric is not available yet.	Wait for the measurement to complete.
SpO <sub>2</sub> T SENSOR OFF <b>Note</b> — The ability of the algorithm to detect this condition depends on the sensor type in use.	Hard	The algorithm has determined that a sensor is connected, but not properly applied to the patient.	<ul style="list-style-type: none"> <li>• Apply the sensor according to the manufacturer's instructions.</li> <li>• If the condition persists, relocate the sensor to a different site on the patient.</li> </ul>
SpO <sub>2</sub> T SENSOR MALF <b>Source - MX40</b>	Hard	Malfunction of the SpO <sub>2</sub> sensor/adapter cable	Replace sensor.
SpO <sub>2</sub> UNKN SENSOR <b>Source - MX40</b>	Hard	The connected SpO <sub>2</sub> sensor and/or adapter cable is not supported by the hardware version.	Use specified sensor and/or adapter cable.
SpO <sub>2</sub> T UPGRADE <b>Source - MX40</b>	Soft	SpO <sub>2</sub> hardware is in upgrade process. Monitoring is not possible.	Wait for the upgrade process to complete.
TELE BATT EMPTY <b>Note</b> — This INOP may also be configured to display as a Red or Yellow Technical Alarm. <b>Source - MX40</b> <b>Note</b> — For Information Center Release L or M, this INOP will appear as "REPLACE BATTERY T".	Hard, Latched	Lithium-ion battery level is critically low. A 10-minute countdown begins. The MX40 will shut down if the condition is not cleared.	Insert a charged lithium-ion battery pack.
TELE BATTERY TEMP <b>Source - MX40</b> <b>Note</b> — For Information Center Release L or M, this INOP will appear as "REPLACE BATTERY T"	Hard	The temperature of the lithium-ion battery is above 55° C or below -5° C.	Replace the lithium-ion battery.
TELE CHECK BATT <b>Source - MX40</b>	Soft	Lithium-ion battery has ≤ 25 charge cycles remaining before reaching the charge cycle maximum limit.	Be aware that the Lithium-ion battery pack will soon need replacement.

## Technical Alarms (INOPs)

Alarm Text	Priority	Condition	What to do
TELE MALFUNCTION  <b>Source - MX40</b>	Hard	MX40 malfunction or self-test failure.	Contact Service to replace the MX40.
TELE REMOVE BATT <b>Source - MX40</b> <b>Note</b> — For Information Center Release L or M, this INOP will appear as "REPLACE BATTERY T".	Hard, Latched	The temperature of the lithium-ion battery is >60° C and the battery must be removed.	<ul style="list-style-type: none"> <li>• Replace the lithium-ion battery.</li> <li>• Dispose of old battery properly.</li> </ul>
TELE SERVICE BATT <b>Source - MX40</b>	Hard	The lithium-ion battery has exceeded the maximum charge cycle limit and reached the end of its useful life.	<ul style="list-style-type: none"> <li>• Replace the lithium-ion battery.</li> <li>• Dispose of old battery properly.</li> </ul>
TELE WEAK SIGNAL  <b>Source - MX40</b>	Soft	<ul style="list-style-type: none"> <li>• Patient is at outer range of the radio coverage area.</li> <li>• The MX40 is receiving a weak signal with high data loss from the AP.</li> <li>• Condition exists for multiple devices in a specific area</li> </ul>	<ul style="list-style-type: none"> <li>• Return patient to the coverage area.</li> <li>• If patient is in close proximity to AP, replace the MX40. Contact service.</li> <li>• The AP covering the specific area is suspect. Contact Service</li> </ul>
TRANSMITTER OFF  <b>Source - MX40</b>	Hard	RF Auto Shutoff after 10 minutes of all leads off and no SpO <sub>2</sub> sensor connected.	<ul style="list-style-type: none"> <li>• Reattach ECG leads to patient.</li> <li>• Reattach SpO<sub>2</sub> sensor.</li> </ul>
UNSUPPORTED LAN  <b>Source - MX40</b>	Hard	The MX40 (WLAN) is connected to the Access Point, but cannot obtain an IP address.	Correct the IP address issue.
WIFI OUT OF RANGE  <b>Source - MX40</b>	Hard	The MX40 (WLAN) is out of range of an access point.	Correct the RF coverage issue.



## 6. ECG and Arrhythmia Monitoring

This section covers the specifics of ECG measurement and the ST/AR Arrhythmia, ST, and QT algorithms used for arrhythmia monitoring.

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## ECG Safety Information

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### Warnings

- The MX40 operates exclusively via a wireless network connection, therefore, it should not be used for primary monitoring in applications where momentary loss of the ECG is unacceptable at the Information Center. It sends ECG and optionally pulse oximetry data to the Information Center, where the Information Center displays real-time patient data, provides alarm annunciation, data storage and review applications. The ECG waveform data, alarms and optionally SpO<sub>2</sub> can always be viewed on the MX40 regardless of the connection to the Information Center.
  - Always confirm MX40 and Information Center observations with clinical observation of the patient before administering interventions.
  - To avoid patient injury, assure that the patient cable is not positioned where leads could become entangled around the patient, or cause choking, strangulation, or inhibit circulation in extremities.
  - Every lead must be secured to an electrode on the patient. Conductive parts of electrodes must not contact earth or other conductive parts.
  - EASI derived 12-lead ECGs and their measurements are approximations to conventional 12-lead ECGs. As the 12-lead ECG derived with EASI is not exactly identical to the 12-lead conventional ECG obtained from an electrocardiograph, it should not be used for diagnostic interpretations.
  - EASI lead placement is supported for adult patients only.
  - Ensure that the patient cable is properly connected to the MX40.
  - Do not mix and match electrodes of different types. In particular, do not use electrodes of dissimilar metals. This helps ensure optimal signal quality.
  - Non-manufacturer supplied accessories and supplies can corrupt the performance of the equipment. Use only AAMI EC-12 compliant electrodes with this device. Use of electrodes that are non-compliant may provide erroneous results.
  - During complete heart block or pacemaker failure (to pace or capture), tall P-waves (greater than 1/5 of the average R-wave height) can be erroneously counted by the arrhythmia algorithm, resulting in missed detection of cardiac arrest.
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### Caution

- To protect the MX40 from damage during defibrillation, to ensure accurate ECG information, and to provide protection against signal noise and other interference, use only ECG electrodes and cables specified by Philips.
  - Philips recommends that you change the lead label only to reflect the physical placement of electrodes. This will ensure a match between the monitored lead and the label, and prevent any possible confusion.
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**Note—** When switching from EASI to standard monitoring, there is a momentary loss of data.

## For Paced Patients

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### Warnings

- The output power of the MX40 and other sources of radio frequency energy, when used in the proximity of a pacemaker, can be sufficient to interfere with pacemaker performance. Due to the shielding effects of the body, internal pacemakers are somewhat less vulnerable than external pacemakers. However, caution should be exercised when monitoring any paced patient.

In order to minimize the possibility of interference, position electrodes, electrode wires, and the MX40 as far away from the pacemaker as possible.

Consult the pacemaker manufacturer for information on the RF susceptibility of their products and the use of their products with the MX40. See the *IntelliVue Information Center Instructions for Use* for additional information on monitoring paced patients.

- When an external pacemaker is being used on a patient, arrhythmia monitoring is severely compromised due to the high energy level in the pacer pulse. This may result in the arrhythmia algorithm's failure to detect pacemaker non-capture or asystole.
- Pacemakers that create fusion beats (pace pulse on top of the QRS complex) cannot be detected by the monitor's QRS detector.

## ECG Safety Information

- For paced patients who exhibit only intrinsic rhythm, the monitor can erroneously count pace pulses as QRS complexes when the algorithm first encounters them, resulting in missed detection of cardiac arrest. The risk of missing cardiac arrest can be reduced by monitoring these patients with the low heart rate limit at or slightly above the basic/demand pacemaker rate. A low heart rate alarm notifies you when the patient begins pacing. Proper detection and classification of the paced rhythm can then be determined.
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**Note—** During defibrillation, monitoring may be temporarily interrupted or distorted. It may take several seconds for the ECG trace to reappear on the screen. After defibrillation, the device will continue to monitor as before; the device settings will not be affected.

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## Measuring ECG

The electrocardiogram (ECG) measures the electrical activity of the heart and displays it on the MX40 and the Information Center as a waveform and a numeric.

In order to compare measured ECG signals, the electrodes (or patient cables) are placed in standardized positions, forming "leads". To obtain ECG signals optimized for use in diagnosis and patient management in different care environments, different leadsets in varying lead placements are used. Standard lead, Hexad and EASI lead placements can be used with the MX40.

The Heart Rate calculation resides in the arrhythmia algorithm on the MX40. Arrhythmia analysis is always turned on for telemetry patients. Arrhythmia analysis is either Basic or Enhanced, depending on the product configuration.

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## Connecting and Positioning ECG Electrodes

Correct lead placement is always important for accurate diagnosis. Especially in the precordial leads, which are close the heart, QRS morphology can be greatly altered if an electrode is moved away from its correct location. Each electrode is color-coded. Use the placement diagrams available on the display of the MX40 and in this section for guidance. Additional lead placement information is available in the *Online Help* at the IntelliVue Information Center.

When placing electrodes on the patient, choose a flat, non-muscular site where the signal will not be impacted by either movement or bones.

Philips recommends that electrodes be changed every 24 hours.

Clinicians will tend to see more motion related artifact on the ECG of ambulatory patients than on patients that are restricted to a bed. Proper skin preparation and electrode application are very important in reducing this problem.

Problems with the ECG signal stem from two main sources:

- 1 Patient-related sources with noise on the waveform caused by clinical considerations such as poor skin prep, dry electrodes, and poor electrode adhesion, as well as by patient motion and muscle artifact
- 2 Frequency-related sources resulting in dropouts from signal disturbances and loss of signal. See Risk Management Considerations p. 15-5.

Even in complex situations where problems overlap, most of the time you'll be able to greatly enhance performance by taking corrective action.

In addition to correct positioning of the electrodes, optimal skin preparation prior to electrode placement will help ensure a clear signal for diagnosis.

- 1 Prepare the patient's skin. Good electrode-to-skin contact is important for a good ECG signal, as the skin is a poor conductor of electricity.
  - Select sites with intact skin, without impairment of any kind.
  - Clip or shave hair from the site as necessary.
  - Wash site with soap and water, leaving no soap residue.  
**Note—** Philips does not recommend using ether or pure alcohol, because they dry the skin and increase the resistance.
  - Dry thoroughly.
  - Use ECG skin preparation paper (abrasive) to remove dead skin cells and to improve the conductivity of the electrode site.

- 2 Check electrodes for moist gel, and attach to the clips. If you are not using pre-gelled electrodes, apply electrode gel to the electrodes before placement.

**Note—** Gel must be moist to provide a good signal.

- 3 Place the electrodes on the patient according to the lead placement you have chosen (see the electrode placement diagrams following). Place the edge down, then "roll down" the rest of the pad. Press firmly around the adhesive edge toward the center.
- 4 Attach the patient cable to the MX40. An ECG waveform and numeric appear on the monitor display.

---

## Selecting the Primary and Secondary ECG Leads

When multilead analysis is used, the MX40 uses the primary and secondary lead selected at the Information Center to compute HR and to analyze and detect cardiac arrhythmias. They are also available for recordings and for display on the Information Center.

Only the primary lead is used if your device is configured for single lead arrhythmia analysis.

You should choose a lead as primary or secondary lead at the Information Center that has the following characteristics:

- the QRS complex should be either completely above or below the baseline and it should not be biphasic
- the QRS complex should be tall and narrow
- the P-waves and T-waves should be less than 0.2 mV



---

## Checking Paced Status

It is important to set the paced status correctly when you start monitoring ECG.

**Note** — Paced status is set at the Information Center and can only be changed at the Information Center.

When Paced is set to On:

- Pacer Algorithm is switched on. This means that pacemaker pulses are not counted as extra QRS complexes.
- The pacer spikes are shown in white.
- The paced symbol is displayed.

When Paced is set to Unconfirmed (IIC iX only):

- Pacer Algorithm is switched on. This means that pacemaker pulses are not counted as extra QRS complexes.
- The pacer spikes are shown in white.
- The paced symbol with ? is displayed.

When Paced is set to Off and your patient has a pacemaker, pace pulses may be counted as regular QRS complexes, which could prevent an asystole event from being detected.

---

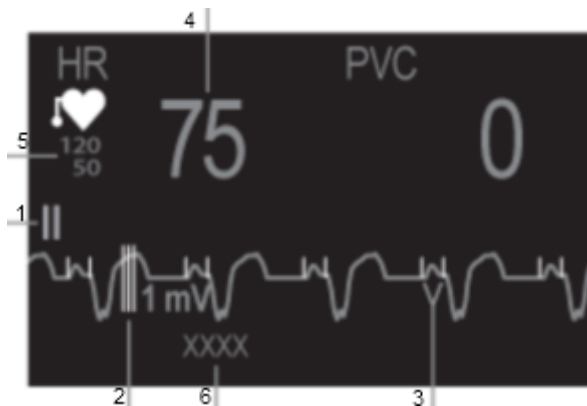
### Warning

- Pace pulse rejection must be switched on for paced patients by setting Paced to On. Switching pace pulse rejection off for paced patients may result in pace pulses being counted as regular QRS complexes, which could prevent an asystole event from being detected. At admission/discharge, always check that paced status is correct for the patient.
  - Some pace pulses can be difficult to reject. When this happens, the pulses are counted as a QRS complex, and could result in an incorrect HR and failure to detect cardiac arrest or some arrhythmias. Make sure that pace pulses are detected correctly by checking the pace pulse markers on the display. Keep pacemaker patients under close observation.
-

## Understanding the ECG Display

# Understanding the ECG Display

Your display may be configured to look slightly different.



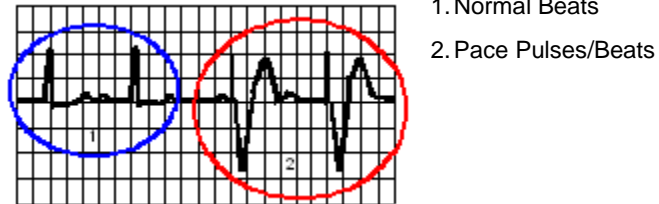
1. Lead label of the displayed wave
2. 1 mV calibration bar
3. Pacer spikes
4. Current heart rate
5. Current heart rate alarm limits
6. EASI lead placement label (located here when active)
7. Paced status

**ECG HR numeric:** This is the heart rate derived from the monitored ECG.

**Pacer Spikes:** The pacer spikes are shown in white.

## Monitoring Paced Patients

An ECG optimized for monitoring a paced patient should look like this:



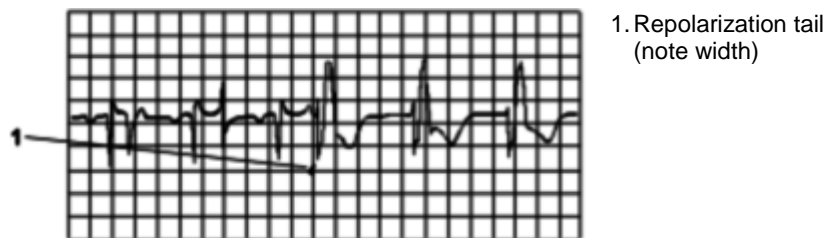
Choose a lead as primary or secondary lead that has these characteristics:

- the normal QRS complex should be either completely above or below the baseline and it should not be biphasic. For paced patients, the QRS complexes should be at least twice the height of pace pulses.
- the QRS complex should be tall and narrow
- the P-waves and the T-waves should be less than 0.2 mV.

## Optimizing Lead Selection for Paced Patients

Some unipolar pacemakers display pace pulses with repolarization tails. These tails may be counted as QRSs in the event of cardiac arrest or other arrhythmias.

If you note a visible repolarization tail, choose a lead that decreases the size of the repolarization tail.



Avoid fusion and pseudofusion beats.



---

## Changing the Size of the ECG Wave

If any of the displayed ECG waves is too small or clipped, you can change the size of the ECG waves on the screen.

Changing the adjustment factor only changes the visual appearance of the ECG wave on the MX40. It does not affect the ECG signal analyzed by the algorithm.

Comparing the wave size to the 1 mV calibration bar on the ECG wave segment can help you get an idea of the true ECG signal strength.

➤ ***To change the size of the ECG waves on the screen by a fixed adjustment factor:***

- 1 Touch the **HR** parameter.
- 2 In the **Setup ECG** menu, scroll to the second page and select **Adjust Size**.
- 3 Select the required adjustment factor from the list.
  - Size X1/2 to halve the wave size
  - Size X1 to display the wave without zoom
  - Size X2 to double the wave size
  - Size X4 to multiply the wave size by fouror
- 4 Touch the **ECG wave** and enter the size from the **Change Wave** menu.
- 5 Select the required adjustment factor from the list.

---

## Choosing EASI or Standard Lead Placement

Choose either standard lead placement or EASI lead placement:

- 1 In the **Setup ECG** menu, select **Lead Placement** to toggle between Standard or EASI.
- 2 Select **Standard** or **EASI**.

**Note** — When changing lead placement, the patient cable must be attached to the MX40.

EASI is shown beside the 1 mV calibration bar on the ECG wave on the display, and EASI is marked on any recorder strips and printouts.

See the sections on Lead Placement for electrode placement diagrams.

---

## Derived 12-lead ECG

### Hexad

When operating with the IntelliVue Information Center iX, the optional Hexad ECG system generates a Mason-Likar 12-lead ECG from a 6-wire leadset (including four limb electrodes and two chest electrodes) placed according to the Mason-Likar 6-electrode placement.

To generate a derived 12-lead ECG using this configuration, 8 out of the 12 leads are directly acquired (I, II, III, aVR, aVL, aVF and the two directly-recorded V leads) and only 4 precordial leads need to be derived. This means that 8 of 12 are identical to the 12 leads acquired using a full set of 10-wire standard ECG lead set. For more information refer to the *12 Lead ECG Monitoring Using a Reduced Lead Set Application Note*, Part Number 452296278591.

---

### Caution

Hexad derived chest leads and their measurements are approximations to the standard ECG, and should not be used for diagnostic interpretation.

---

### EASI

The EASI system, a method of deriving 12ECG leads using a five-electrode configuration (4 monitoring electrodes and a ground electrode), has been developed to better address the goals and challenges of continuous ECG monitoring. EASI monitoring makes it possible to obtain 12-lead ECG information under continuous monitoring conditions across the continuum of care. The EASI method of obtaining a 12-lead ECG requires only five electrodes. The electrodes are placed on the upper sternum (S), the lower sternum (E) at the level of the fifth intercostal space, and on the right and left midaxillary lines (I and A) at the same level as the lower sternum electrode. A fifth ground electrode can be placed anywhere.

## ECG Configuration

The MX40 supports 3-, 5-, and 6-wire patient cables. The 5-wire patient cable can be used for either standard or EASI electrode configurations. The 6-wire patient cable can be used for either standard or Hexad electrode configurations. The MX40 detects the patient cable type attached and automatically determines the ECG measurement and transmitted leads.

**Note**—The labels and colors of the ECG electrodes differ according to the standards that apply for your hospital. The electrode placement references and illustrations in this chapter use the AAMI labels and colors. See the table below for additional label and color information.

Electrode Labels			Electrode Colors	
AAMI	EASI	IEC	AAMI	IEC
RA	I	R	White	Red
LA	S	L	Black	Yellow
LL	A	F	Red	Green
RL	N	N	Green	Black
V/Va	E	C/Ca	Brown	White
Vb		Cb	Brown/White	White/Blue

Arrhythmia analysis resides in the arrhythmia algorithm on the MX40. Arrhythmia analysis is always turned on for telemetry patients unless operating with the IntelliVue Information Center iX, where it can be turned off. Arrhythmia analysis is either Basic or Enhanced (optional).

## ECG Leads Monitored

Depending on the patient cable connected to the MX40, a different set of viewable leads are available at the MX40 and the Information Center. The MX40 can source up to four raw ECG waves to the Information Center.

If you are using ...	these leads can be selected at the MX40 and the Information Center
3-wire	I, II, III Sourced (raw) waves are received as: Channel 1 = I, II, or III Factory Default is II.
5-wire (Standard mode)	I, II, III, aVR, aVL, aVF, MCL and V Sourced (raw) waves are received as: Channel 1 = II Channel 2 = III Channel 3 = MCL Factory Defaults are II, V, III.
5-wire (EASI mode)	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 In EASI mode, the sourced (raw) waves are received as: Channel 1 = Vector 1 (A-I) Channel 2 = Vector 2 (A-S) Channel 3 = Vector 3 (E-S) Factory Defaults are II, V2, III, V5. Arrhythmia monitoring is performed only on the primary and secondary leads selected at the Information Center, although you can view and perform ST analysis on all 12 EASI derived leads.



If you are using ...	these leads can be selected at the MX40 and the Information Center
6-wire	<p>I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6, V7, V8, V9, V3R, V4R, V5R.</p> <p>Sourced (raw) waves are received as:</p> <p>Channel 1 = II</p> <p>Channel 2 = III</p> <p>Channel 3 = Va</p> <p>Channel 4 = Vb</p> <p>Factory Defaults are II, Va = V2, III, Vb = V5.</p> <p>The two chest leads, Va and Vb, can be placed on the patient in any of the V lead positions (V1 through V9, V3R, V4R, V5R). Lead assignment is available at the Information Center. When unassigned, the chest leads use the defaults.</p> <p><b>Note—</b> The lead label assigned to Vb cannot be selected for Va even though Vb does not appear to be used.</p> <p>When display of the pleth wave is enabled at the Information Center, the second chest lead (Vb) is not available for monitoring.</p>
6-wire (Hexad Mode)	<p>I, II, III, MCL, aVR, aVL, aVF, V1-V6.</p> <p>Factory Defaults = Off, V1/V3, V1/V4, V1/V5, V2/V4, V2/V5, V3/V5, V3/V6</p> <p>Derived leads are labeled, e.g. dV3.</p>

## Reconstructed Leads

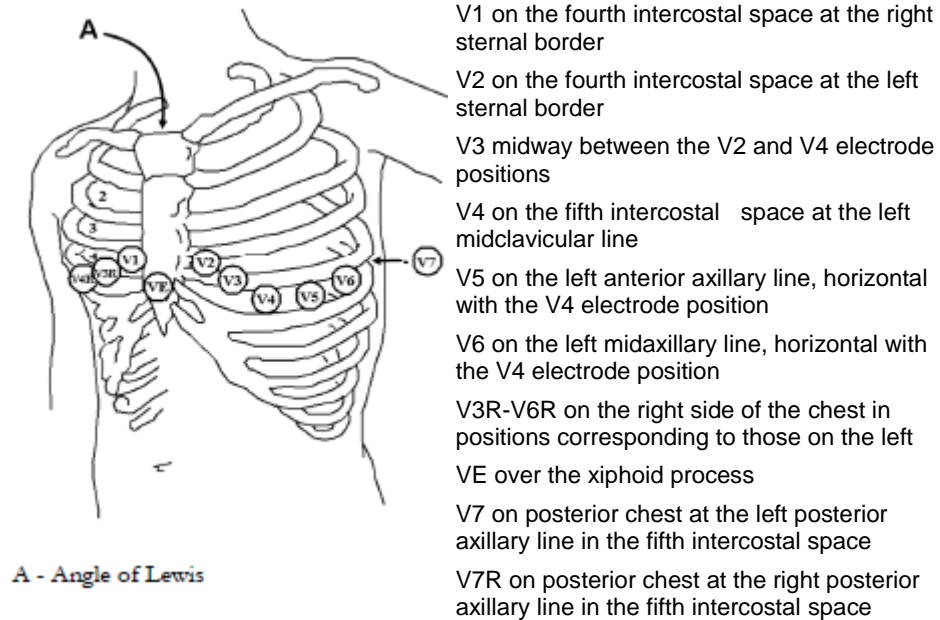
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## Reconstructed Leads

Reconstruction of leads from the sourced wave is defined by the calculations in the following table. EASI reconstructed leads are a linear combination of all three raw EASI leads

ECG Lead			Clinical Calculations in terms of electrodes
3-wire	5-wire Standard	6-wire	
I	I	I	LA-RA
II (default)	II (default)	II (default)	LL-RA
III	III (default)	III (default)	LL-LA
-	MCL		V-LA, where V=C
-	aVR	aVR	$RA-(LA+LL)/2$
-	aVL	aVL	$LA-(RA+LL)/2$
-	aVF	aVF	$LL-(LA+RA)/2$
-	V (default)		$V-(RA+LA+LL)/3$ , where V=C
		Va	$Va-(RA+LA+LL)/3$ , where Va=V2 (default) position
		Vb	$Vb-(RA+LA+LL)/3$ , where Vb=V5 (default) position

## Chest Electrode Placement



For accurate chest electrode placement and measurement, it is important to locate the fourth intercostal space.

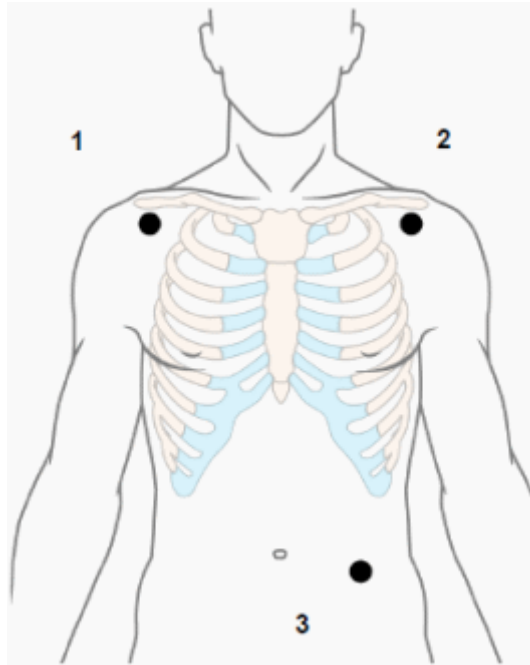
### ➤ ***To locate the fourth intercostal space:***

- 1 Locate the second intercostal space by first palpating the Angle of Lewis (the little bony protuberance where the body of the sternum joins the manubrium). This rise in the sternum is where the second rib is attached, and the space below this is the second intercostal space.
- 2 Palpate and count down the chest until you locate the fourth intercostal space.

## 3-Wire Placement

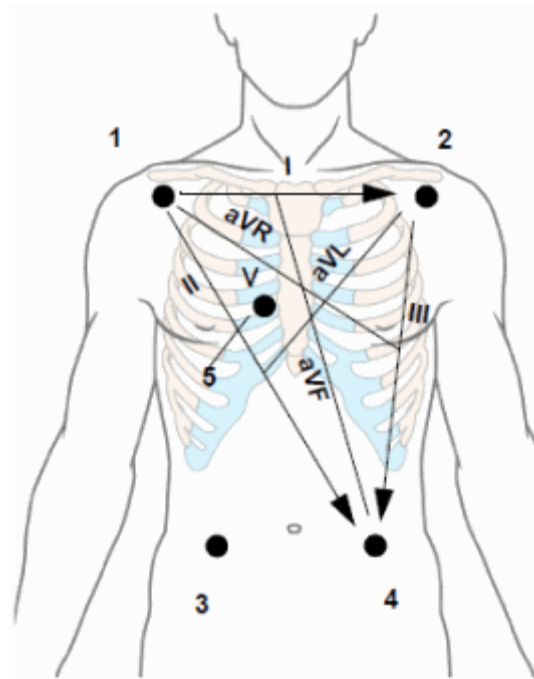
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### 3-Wire Placement



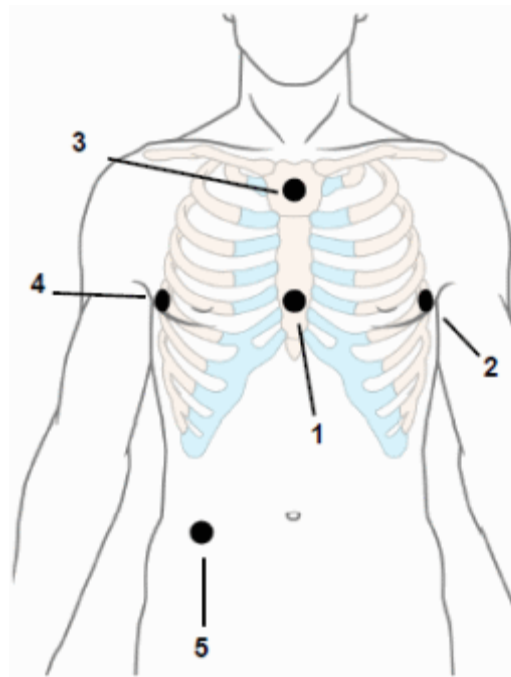
1. RA - directly below the clavicle and near the right shoulder
2. LA -directly below the clavicle and near the left shoulder
3. LL - on the left lower abdomen

## 5-Wire Placement (Standard)



1. RA directly below the clavicle and near the right shoulder
2. LA directly below the clavicle and near the left shoulder
3. RL on the left lower abdomen
4. LL on the right lower abdomen
5. V on the chest, the position depends on your required lead selection.
  - V1 on the fourth intercostal space at the right sternal border
  - V2 on the fourth intercostal space at the left sternal border
  - V3 midway between the V2 and V4 electrode positions
  - V4 on the fifth intercostal space at the left midclavicular line
  - V5 on the left anterior axillary line, horizontal with the V4 electrode position
  - V6 on the left midaxillary line, horizontal with the V4 electrode position

## 5-Wire Placement (EASI)



1. E (V) on the lower sternum at the level of the fifth intercostal space
2. A (LL) on the left midaxillary line at the same level as the E electrode
3. S (LA) on the upper sternum
4. I (RA) on the right midaxillary line at the same level as the E electrode
5. N (Reference) can be anywhere, usually below the sixth rib on the right hip

**Make sure that the S and E electrodes line up vertically on the sternum, and that the I, E and A electrodes align horizontally.**

---

## 6-Wire Placement

For a 6-lead placement use the positions from the 5-lead diagram above but with two chest leads. The two chest leads, Va and Vb, can be positioned at any two of the V1 to V6 positions shown in the chest electrode diagram below.

The default position of Va - the brown lead - is at the V2 position.

The default position for Vb - the brown/white lead - is at the V5 position.

The lead placement for the Va and Vb lead labels must be appropriate. If your unit uses other precordial leads for Va and Vb, they may be assigned in Unit Settings at the Information Center as defaults for your whole unit, or you may need to assign the new positions on a per-patient basis in the Patient Window at the Information Center.

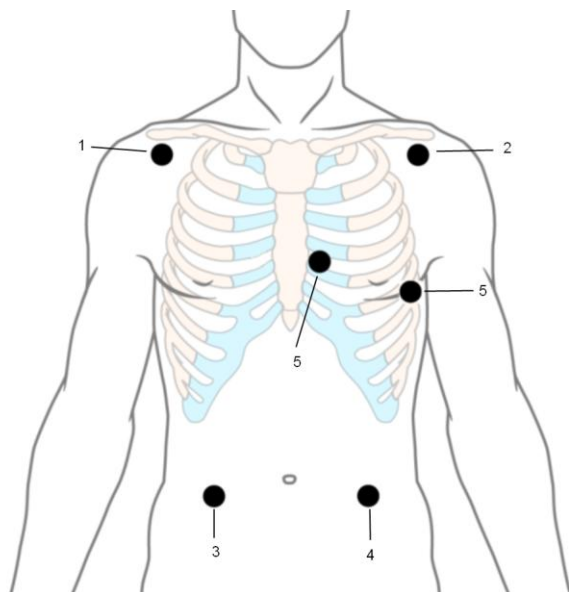
### Selecting Positions of Va and Vb Chest Leads

The two chest leads for the 6-lead placement can be positioned at any two of the V1 to V9 and V3R, V4R and V5R positions. Select the positions you have used in the Patient Window at the Information Center, so that the chest leads will be correctly labeled.

## 6-Wire Placement (Hexad)

### 6-Wire Placement (Hexad)

The diagram below shows the Mason-Likar Placement using 6 electrodes. Chest electrodes may be placed in additional positions as presented at the IntelliVue Information Center iX for chest lead pair selection.



**Note** — In Hexad mode, V leads are chosen in pairs at the IntelliVue Information Center iX.

1. RA directly below the clavicle and near the right shoulder
  2. LA directly below the clavicle and near the left shoulder
  3. RL on the left lower abdomen
  4. LL on the right lower abdomen
  5. V on the chest, the position depends on your required lead selection. The typical position is V1, although this may vary according based on your hospital's protocol.
- V1 on the fourth intercostal space at the right sternal border
  - V2 on the fourth intercostal space at the left sternal border
  - V3 midway between the V2 and V4 electrode positions
  - V4 on the fifth intercostal space at the left midclavicular line
  - V5 on the left anterior axillary line, horizontal with the V4 electrode position
  - V6 on the left midaxillary line, horizontal with the V4 electrode position



---

## Monitoring during Leads Off

ECG Fallback and Extended monitoring states are supported for the MX40 when the primary and/or secondary leads are in a "Leads Off" INOP condition. Both of these states are entered into after 10 seconds of "Leads Off" in an attempt to maintain monitoring and arrhythmia analysis.

### ECG Fallback

ECG Fallback occurs when the primary lead is in "Leads Off" for 10 seconds and a secondary lead is available.

#### Multilead Analysis

If there is a "Leads Off" technical alarm in the primary lead for > 10 seconds, the active secondary lead becomes the primary lead. The arrhythmia algorithm switches the leads on the display, but relearn does not occur. When the "Leads Off" condition is corrected, the leads are switched back to their original state.

#### Single Lead Analysis

For single lead analysis, if there are two leads available, the secondary lead is made the primary lead until the "Leads Off" condition is corrected. The arrhythmia algorithm performs a relearn using the available lead.

#### Extended Monitoring

If both the primary and secondary leads are in a "Leads Off" condition, the ECG source on the MX40 will switch to any available lead. Relearning will occur in this condition.

#### Fallback for EASI

If one of the derived EASI leads is in a technical alarm condition, a flat line is displayed. After 10 seconds, the directly acquired EASI AS, EA, or AI lead, depending on which is available, is displayed. Arrhythmia relearn is performed with transition to or from EASI Fallback monitoring using the available lead(s).

### Relearning

Whenever there is a "Leads Off" condition for more than 60 seconds, the arrhythmia algorithm performs a Relearn using the available leads.

## Monitoring during Leads Off

---

### Warning

Since Relearn happens automatically, if learning takes place during ventricular rhythm, the ectopics can be incorrectly learned as the normal QRS complex. This can result in missed detection of subsequent events of V-Tach and V-Fib. For this reason, you should:

- 1 Respond promptly to any technical alarm.
  - 2 Ensure that the arrhythmia algorithm is labeling beats correctly.
-

---

# ST/AR Arrhythmia Monitoring

## ST/AR Arrhythmia Algorithm

### Indications for Use

The ST/AR Arrhythmia Algorithm is indicated for use in instances where the clinician decides to monitor cardiac arrhythmias of adult and pediatric patients and/or the ST segment of adult patients to gain information for treatment, monitor the adequacy of treatment, or to exclude causes of symptoms.

### How the ST/AR Algorithm Works

ST/AR multi-lead analysis is performed on the user-selected primary and secondary leads. If only one lead is available for multilead, ST/AR analysis is performed on the single available lead.

Arrhythmia analysis consists of several steps:

- 1 The ECG signal is pre-processed to filter out baseline wander, muscle artifact, and signal irregularities. In addition, if the Paced status = On, pace pulses are detected then rejected from the processing to avoid seeing them as QRS beats.
- 2 Beat detection to locate the QRS complexes for further analysis.
- 3 Feature measurement such as R-wave height, width, and timing.
- 4 Beat classification. Templates are created and are matched to incoming beats, and the appropriate beat label is determined.
- 5 Atrial Fibrillation Detection. Analyzes the RR intervals and P waves.
- 6 Ventricular Fibrillation Detection. Looks for a flutter or sinusoidal wave pattern in both ECG channels
- 7 Rhythm and alarm detection. Beat labels are used to produce the values and events needed to generate rhythms and alarms.

Working in parallel with beat detection and classification, a separate detector examines continuously for ventricular fibrillation, asystole, and noise.

The quality of the ECG signal is important for accurate arrhythmia analysis. The section below provides guidelines for optimizing signals for arrhythmia analysis.

## ST/AR Arrhythmia Monitoring

For additional information on the ST/AR Algorithm, refer to the *Arrhythmia Monitoring ST/AR Algorithm Application Note*.

### Aberrantly-Conducted Beats

As P-waves are not analyzed, it is difficult and sometimes impossible for the monitor to distinguish between an aberrantly-conducted supraventricular beat and a ventricular beat. If the aberrant beat resembles a ventricular beat, it is classified as ventricular. You should always select a lead where the aberrantly-conducted beats have an R-wave that is as narrow as possible to minimize incorrect calls. Ventricular beats should look different from these 'normal beats'. Instead of trying to select two leads with a narrow R-wave, it may be easier to just select one lead and use single lead arrhythmia monitoring. Extra vigilance is required by the clinician for this type of patient.

### Atrial Fibrillation Alarm

The MX40 performs atrial fibrillation analysis using information about the RR irregularity, PR interval variability, and P-wave variability.

In order to generate an Afib alarm the following criteria must be detected for 1 minute:

- normal beat RR intervals must be irregular
- PR interval deviation must be large
- P-wave region must not match well

Atrial fibrillation analysis is only available for adult patients and atrial fibrillation detection cannot be performed on PVCs or Paced beats.

An **\*End AFIB** alarm will occur when no atrial fibrillation waveform is detected for a configured delay time.

Since most atrial flutters have regular RR intervals, they cannot be detected by the atrial fibrillation algorithm.

An **\*AFIB** alarm can be falsely detected in the presence of:

- sinus arrhythmia
- muscle noise, or
- electrode motion artifact

## Intermittent Bundle Branch Block

Bundle branch and the other fascicular blocks create a challenge for the arrhythmia algorithm. If the QRS during the block changes considerably from the learned normal, the blocked beat may be incorrectly classified as ventricular, causing false PVC alarms. You should always select a lead where the bundle branch block beats have an R-wave that is as narrow as possible to minimize incorrect calls. Ventricular beats should look different from these 'normal beats'. Instead of trying to select two leads with a narrow R-wave, it may be easier to just select one lead and use single lead arrhythmia monitoring. Extra vigilance is required by the clinician for this type of patient.

## ECG and Arrhythmia Alarm Overview

The ECG and arrhythmia alarms available depend on which measurements are switched on, and the arrhythmia option enabled for your MX40.

- Cardiotach alarms are available when HR is on and the active alarm source is ECG, but arrhythmia is switched off.
- Basic arrhythmia alarms are available when Arrhythmia is switched on.
- Enhanced arrhythmia alarms are available when Arrhythmia is switched on and the Enhanced Arrhythmia option has been enabled for your MX40.

To check your enabled settings, view the **Standby** screen.

## ST/AR Arrhythmia Monitoring

Cardiotach Alarms	Additional Alarms with Basic Arrhythmia Option	Additional Alarms with Enhanced Arrhythmia Option
***Asystole ***Ventricular Fibrillation/ Tachycardia ***Extreme Bradycardia ***Extreme Tachycardia */**High heart rate */**Low heart rate	***Ventricular Tachycardia *Pacer Not Capture *Pacer Not Pacing *PVCs/min HIGH (PVC > limit/min)	*Afib *End Afib *Supraventricular Tach *Missed Beat *Pause *Irregular HR *End Irregular HR *Ventricular Rhythm *Run PVCs High *Pair PVCs *R-on-T PVCs *Ventricular bigeminy *Ventricular trigeminy *Non-sustain VT *Multiform PVCs

**Note** — When operating with the IntelliVue Information Center Release N or earlier, the ST/AR Arrhythmia Algorithm operates and generates alarms independently at both the MX40 and the Information Center. Therefore, you may see slight differences between the two, even though the alarm settings and limits are the same.

## Using ECG Alarms

At the Information Center, ECG alarms can be switched on and off and the high and low alarm limits changed just like other measurement alarms, as described in the Alarms chapter. Special alarm features which apply only to ECG are described here.

### Extreme Alarm Limits for Heart Rate

The extreme rate alarms, Extreme Tachy and Extreme Brady, are set at the Information Center by adding a set value (the D value) to the high and low alarm limits.



You need to know which value has been configured for your monitor. Changing the high and low alarm limits automatically changes the extreme alarm limits within the allowed range.

## Arrhythmia Alarm Settings

Some arrhythmia alarms can be turned off at the Information Center depending its configuration. They are:

**Non-Sustain VT, Vent Rhythm, Run PVCs, Pair PVCs, R-On-T PVC, V.Bigeminy, V.Trigeminy, Multif.PVCs, Pause, SVT, HR High, HR Low Irregular HR (IHR), Missed Beat, PVCs/min, Pacer Not Capture, Pacer Not Pacing, and Afib.**

Alarms that have been turned off at the Information Center will appear as off in the Arrhythmia menu of the MX40, but they are not accessible, nor can you change limits locally.

## Yellow Arrhythmia Alarms

Yellow arrhythmia alarms are short yellow alarms specific to arrhythmia-related patient conditions. Depending on your Information Center configuration, they may be shown with one or two stars. The heart rate alarms (High HR and Low HR) can be configured as short yellow or standard yellow alarms. When they are standard yellow alarms they exist independently of the other arrhythmia alarms and no timeout periods apply.

---

### Warning

When arrhythmia analysis is on, all yellow ECG and arrhythmia alarms are short yellow alarms (one-star). This means that the alarm tones (if volume is on) are active for six seconds only, after which the blinking numeric and the alarm message remain for up to three minutes. The only exception to this are the HR High and Low alarms which can be configured as standard yellow alarms. Red alarms behave as usual.

---

## Viewing Arrhythmia Waves

### ➤ *To view arrhythmia beat labels:*

- 1 Go to the **Setup ECG** menu.
- 2 Select **Arrhythmia**.
- 3 Change **Annotate Arrhy** from **Off** to **On**. Beat labels will be annotated above the ECG wave and Delayed will appear beside it.

### ➤ *To return to the normal ECG primary lead display:*

- 1 Select **Annotate Arrhy**.
- 2 Change to **Off**.
- 3 Exit from the **Setup ECG** menu.

## Arrhythmia Beat Labels

Arrhythmia beat labels tell you how the monitor is classifying beats.

**N** = Normal

**V** = Ventricular Ectopic

**S** = Supra-ventricular Premature

**P** = Paced

**'** = Pacer spike

**"** = Biventricular Pacer Spike

**L** = Learning patient's ECG

**A** = Artifact (noisy episode)

**?** = Insufficient information to classify beats

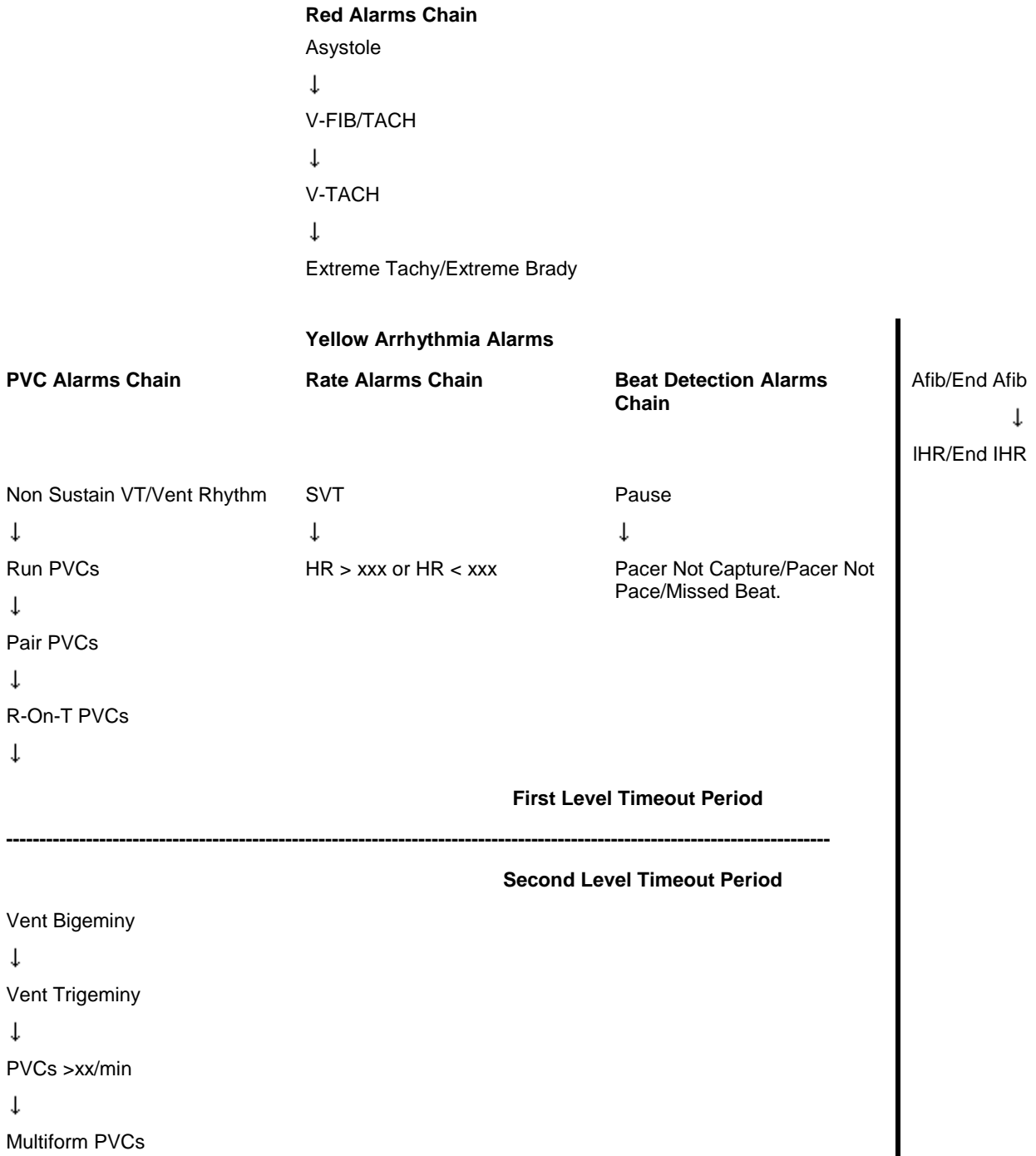
**I** = Inoperative condition (e.g., LEADS OFF)

**M** = Pause or missed beat



## Enhanced Arrhythmia Chain

The diagram below shows the alarm condition priority chains for enhanced arrhythmia. The alarm conditions in each category are prioritized according to the level of seriousness.



## Basic Arrhythmia Chain

The diagram below shows the alarm condition priorities for basic arrhythmia and the timeout levels for yellow alarm conditions.

### Red Alarms

Asystole



V-FIB/TACH



V-TACH



Extreme  
Tachy/Extreme  
Brady



### Yellow Arrhythmia Alarms

#### PVC Alarms Chain

#### Beat Detection Alarms Chain

Pacer Not  
Capture/Pacer  
Not Pace

#### Rate Alarms Chain

HR > xxx or HR < xxx

#### First Level Timeout Period

#### Second Level Timeout Period

PVCs >xx/min

## Learning

The arrhythmia system's goal is to learn the patient's normal complexes so it can differentiate abnormal beats. This "learning" process uses the 15 first valid beats (for example, free from noise) encountered during the learning phase.

While the system is learning the complex, the delayed arrhythmia wave displays the beat label "L".

## Learning Phase

A learning phase involves the system learning the patient's dominant complexes. During a learning phase:

- Alarm timeout periods are cleared.
- Stored arrhythmia templates are cleared.
- Asystole, Vfib, and HR alarms (when there are enough beats to compute the HR) are active.
- All other alarms are not active.

## Single Lead Analysis

If single lead analysis is selected, the arrhythmia system begins learning whenever:

- ECG monitoring is initiated.
- The **Relearn Arrhy** control is activated. See Initiating Arrhythmia Relearning Manually p. 6-36.
- The ECG Lead or Lead Label is changed manually, or when Fallback occurs. See Fallback.
- A "LEADS OFF" INOP condition (that has been active for >60 seconds) ends.
- When the MX40 re-associates with the Information Center.

## Multilead Analysis

If multilead analysis is selected, the arrhythmia system begins a learning on *both* leads whenever:

- ECG monitoring is initiated.
- The **Relearn Arrhy** control is activated (see Initiating Arrhythmia Relearning Manually p. 6-36).
- There has been a Leads Off INOP condition (that has been active for >60 seconds) for both leads, and the condition ends in either lead.
- When the MX40 re-associates with the Information Center.

## Multilead Analysis With Changes in One Lead

Since the arrhythmia system uses more than one lead for analysis, if there is a change in one lead, the system does a relearn only on the affected lead. This happens whenever:

- An ECG lead or label is changed.

## ST/AR Arrhythmia Monitoring

- A Leads Off INOP condition (that has been active for >60 seconds) ends.

**Note** — During this learning phase the system will continue monitoring using the operative lead. Therefore, the delayed arrhythmia wave is not labeled "L". In addition:

- Alarm timeout periods are maintained.
- Stored arrhythmia templates are maintained for the operative lead.
- All alarms turned on are active.

## EASI ECG Monitoring

Whenever there is an INOP condition, the arrhythmia algorithm performs a Relearn, using the available lead.

---

### Warning

Since Relearn happens automatically, if learning takes place during ventricular rhythm, the ectopics may be incorrectly learned as the normal QRS complex. This may result in missed detection of subsequent events of V-Tach and V-Fib. For this reason, you should:

- 1 Respond to the INOP message (for example, re-connect the electrode(s)).
  - 2 Ensure that the arrhythmia algorithm is labeling beats correctly.
- 

## Initiating Arrhythmia Relearning Manually

To initiate relearning manually, in the **Setup ECG** menu, select **Relearn Arrhy**.

- While the monitor is learning, if annotate arrhythmia is On, the delayed arrhythmia wave displays the beat label **L**.
- Next, the monitor determines the dominant rhythm. The beats are labeled **N**.

After relearning is complete, you should check the delayed arrhythmia wave to ensure that the algorithm is labeling the beats correctly. See Arrhythmia Beat Labels p. 6-32.

If beats are still not classified correctly, check that the ECG is optimized for arrhythmia monitoring. You may need to select a different lead or change the electrodes or electrode positions if there is excessive noise, unstable voltage, low amplitude, or large P- or T-waves.

---

# ST/AR ST Analysis Algorithm

## Introduction

The intended use of the ST/AR ST Analysis algorithm is to monitor an adult patient's ECG for ST segment elevation or depression and produce events/alarms for all possible ECG leads. The ST Analysis algorithm is capable of monitoring paced and non-paced adult patients.

The ST/AR ST algorithm monitors ST segment elevation or depression for each available telemetry ECG lead and produces events/alarms simultaneously.

*Note*—The ST Analysis algorithm does not analyze ventricularly paced or ventricular ectopic beats.

---

## Warning

This device provides ST level change information; the clinical significance of the ST level change information needs to be determined by a physician.

---

ST values update with every measurement period and enunciate, depending upon the severity of the change, events and alarms as they are detected.

The ST/AR ST algorithm is approved for use only with adult non-paced and atrially-paced patients.

---

## Caution

Some clinical conditions may make it difficult to achieve reliable ST monitoring, for example:

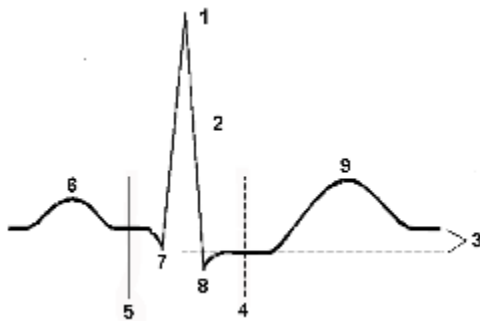
- if you are unable to select a lead this is not noisy
  - if arrhythmias such as atrial fib/flutter are present, which may cause an irregular baseline
  - if the patient is continuously ventricularly paced
  - if the patient has left bundle branch block
-

## The Measurements Overview

The ST/STE measurement for each beat complex is the vertical *difference* between two measurement points. The isoelectric point provides the baseline for both measurements.

The ST measurement uses the isoelectric point and the ST point. The ST point is positioned with reference to the J-point.

The STE measurement uses the isoelectric point and the J point.



1. R-wave peak at 0 msec
2. J point
3. Difference = ST value
4. ST measurement point. Default = J+60 msec
5. Isoelectric point. Default = -80 msec
6. P
7. Q
8. S
9. T

You can manually adjust the ST/STE measurements on the Information Center's Measurements application.

## Turning ST or STE On and Off

ST and STE analysis can be turned on and off independently. You would turn ST/STE monitoring off if:

- You are unable to get any lead that is not noisy.
- Arrhythmias such as atrial fib/flutter cause irregular baseline.
- The patient is continuously ventricularly paced.
- The patient has left bundle branch block.

### ➤ **To turn all ST or STE monitoring on or off at the IntelliVue Information Center iX:**

- 1 Select the Measurements ST page.
- 2 Click the **I/O ST** or **I/O STE Analysis** button to toggle ST or STE Analysis on or off as appropriate.

➤ **To turn ST monitoring on or off at the IntelliVue Information Center Release N:**

- 1 From the Patient Window, click the **All Controls** button.
- 2 From the All Controls Window, click the **ST Setup** button.
- 3 From the ST Setup Window, click **ST On/Off** as appropriate.

## Displayed ST Data

ST data displays as values in the Patient Sector and Patient Window at the Information Center. At the MX40, three ST values can be displayed below the ECG wave. A positive value indicates ST segment elevation; a negative value indicates ST segment depression. You can view ST data at the MX40 if ST is assigned to a numeric area. Up to 3 values can display in the assigned space. If more than three values are available, the last value will rotate.

### Displayed STE Data

STE Data can only be displayed in the Measurements application STE page at the Information Center iX.

**Note** — ST/STE data and alarms are only displayed at the MX40 when operating with IntelliVue Information Center iX.

## ST Lead Groups

ECG Leads are clinically grouped as follows:

ST Lead Group	ECG Leads
Inferior	II, III, aVF
Lateral	I, aVL, V5, V6
Antero-lateral	I, aVL, V4, V5, V6
Anterior	V1, V2, V3, V4
Septal	V1, V2, V3
Right	V3R, V4R, V5R
Posterior	V7, V8, V9

You can change the group displayed using the **ST Views** menu.

## Derived 12 Lead ECG

In view of the high degree of redundancy among the standard 12-lead ECG leads, it is quite conceivable that a more practical leadset with a smaller number of judiciously chosen leads can be used to reconstruct the missing leads. For Hexad derived 12-lead the-6 electrode configuration is the feasibility of deriving additional chest leads if the two chest electrodes are placed in several pre-specified standard precordial locations. Using a standard 5-electrode set in EASI lead placement you can monitor up to 12 standard ECG leads simultaneously and continuously at the bedside. EASI provides a monitoring method for trending ST segment changes that can provide an early indication of ischemia.

---

### Caution

Derived ECG and their measurements are approximations to the standard ECG, and should not be used for diagnostic interpretation.

---

## EASI ST Analysis

With EASI monitoring, ST analysis is performed on up to 12 leads, and an additional value of ST index is calculated and displayed. Assessment of EASI-derived 12-lead ST measurement is recommended for adult patients that meet the following parameters:

- Ages: 33-82 years
- Heights: 147 to 185 cm (58 to 73 in)
- Weights: 53 to 118 kg (117 to 261 lbs)
- Height to Weight Ratios: 1.41 to 2.99 cm/kg (0.25 to 0.54 in/lb)

For additional information on ST monitoring, refer to the *ST Segment Monitoring Application Note*, Part Number 452296278611.

ST values are presented in the patient sector and Patient Window for EASI derived leads along with STindx (ST Index). STindx is a summation of three ST segment measurements, using the leads that can indicate ST segment changes in the different locations of the heart:

- anterior lead V2
- lateral lead V5
- inferior lead aVF



## HEXAD ST Analysis

When operating with the IntelliVue Information Center iX, the optional Hexad algorithm generates a Mason-Likar 12-lead ECG from a 6-wire leadset (including four limb electrodes and two chest electrodes) placed according to the Mason-Likar 6-electrode placement.

To generate a derived 12-lead ECG using this configuration, 8 out of the 12 leads are directly acquired (I, II, III, aVR, aVL, aVF and the two directly-recorded V leads) and only 4 precordial leads need to be derived. This means that 8 of 12 are identical to the 12 leads acquired using a full set of 10-wire standard ECG lead set. For more information refer to the *12 Lead ECG Monitoring Using a Reduced Lead Set Application Note*, Part Number 452296278591.

## ST Alarms

ST Alarms are yellow alarms. They are announced after exceeding alarm limits for one minute. ST Alarm Limits can only be set at the Information Center. Each ST lead has its own alarm limit. ST alarms are triggered when an ST value exceeds its limit for more than one minute. Turning ST Alarms off turns off alarms for all ST leads.

## STE Alarms

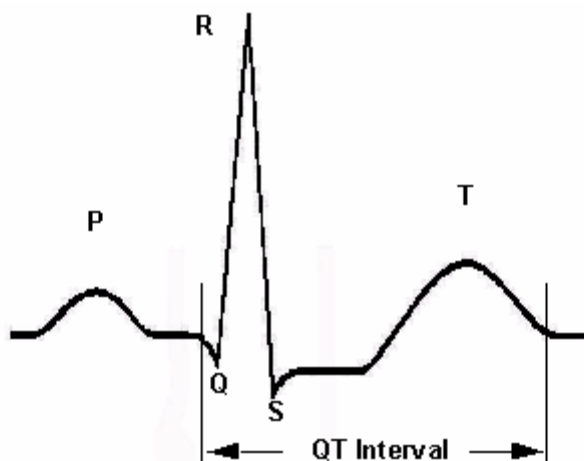
The STE Alarm is a yellow alarm. It is announced after exceeding alarm limits for one minute. It can be turned on and off at the Information Center, however its limits are not adjustable. The STE alarm limits are gender specific and can be set individually for limb leads, V2/V3 leads, and V1/V4/V5/V6 leads. The default values, for example on V2 and V3 1.5 mm for females and 2.0 mm for males, are based on the recommendations from the American Heart Association and American College of Cardiology.

The ST Elevation measurements with automated J-point determination generate ST Elevation alarms, in addition to the ST measurements at the user-defined ST point (J+offset), which may be useful for ST depression alarms. When ST and STE analysis are both in use, this may result in redundant alarms for ST elevations. Because of the different measurement points, there may be different values obtained. Thus there could be an ST alarm and an STE alarm but the STE alarm may announce sooner based upon the values obtained.

## QT Interval Monitoring

Of special concern for QT monitoring is the administration of QT prolonging drugs to patients identified with risk factors for Torsade de Pointe. Females, older patients and patients with bradycardia, impaired left ventricular function (ischemia, left ventricular hypertrophy), hypokalemia and hypomagnesemia are in this increased risk category.

QT interval monitoring can assist in the detection of prolonged QT interval syndrome. The QT interval in an ECG lead is the time interval from the onset of the earliest deflection in the QRS complex to the end of the T wave. For patients being monitored by the MX40, the Information Center measures the QT interval once every minute during startup, during the learning phase and on lead mode change. After that the Information Center updates the QT values every five minutes.



The QT interval has an inverse relationship to heart rate. Faster heart rates shorten the QT interval and slower heart rates prolong the QT interval. To correct the QT interval for heart rate the Information Center uses the Bazett correction formula by default. Your system, however, may be set up to use the Fridericia correction formula as an alternative. The heart rate corrected QT interval is abbreviated as QTc.

**Note** — When operating with the IntelliVue Information Center Release N or earlier, QT Data is not displayed at the MX40

## Intended Use

The intended use of the ST/AR QT/QTc analysis is for use by the physician in the risk assessment process indicated for pediatric and adult patients with and without symptoms of arrhythmia. QT measurement is intended to be used by qualified health professionals in hospital or clinical environments. Composite QT (single or multi-lead derived) measures the interval only and is not intended to produce any interpretation or diagnosis of those measurements. Additional information regarding QT monitoring can be found in the *QT Interval Monitoring Application Note*, Part Number 452296278601.

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### Warning

The device provides QT and QTc interval change information; the clinical significance of the QT and QTc interval change information should be determined by a clinician.

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## How the QT Analysis Algorithm Works

The Information Center measures the QT values once every minute during startup. Subsequently, the Information Center updates the QT values every five minutes. Normal or atrial paced beats and beats with a similar morphology are averaged to form a representative waveform for further processing. Normal beats followed by a premature QRS will be excluded from the measurements to prevent the premature beat from obscuring the end of the T-wave. If the algorithm cannot form a representative waveform, for example because the morphology of the beats is too varied, the Information Center generates a Cannot Analyze QT INOP when it detects two consecutive invalid 5 minute values. This is also the case if normal beats have been falsely labeled so that the algorithm does not have enough valid beats to make QT measurements. No QT value is calculated if the QT-HR is >150 bpm (Adult) or >180 bpm (Pediatric).

Because of the different algorithm approaches, a QT/QTc measurement from a diagnostic 12-lead program may differ from the realtime measurement.

For QT interval monitoring to be effective, basic or enhanced arrhythmia monitoring must be on.

## Adjusting QT Settings

For patients being monitored by the MX40, you can turn QT Monitoring on/off and adjust QT settings at the IntelliVue Information Center.

### ➤ ***To turn QT Monitoring on/off at the IntelliVue Information Center Release N:***

- 1 From the Patient Window, click the **All Controls** button.
- 2 From the All Controls Window, click the **QT Setup** button.
- 3 From QT Setup, click the **QT Analysis On** checkbox.

QT analysis is on when a checkmark displays in the check box. When the QT measurement is on, a QT status message is displayed in the QT Setup window, along with the current values for QT, QTc, dQTc and QT-HR. The lead labels indicating the leads used to calculate the baseline and current values also appear.

### ➤ ***To turn QT Monitoring on/off at the IntelliVue Information Center iX:***

- 1 Select the **Measurements** button from the Main Setup Window.
- 2 From the Measurements Window, select **QT**.
- 3 Click the **I/O QT Analysis** button to toggle on or off as appropriate.

The table below provides descriptions for each of the QT measurement descriptions.

Measurement	Definition
QT	QT interval in milliseconds. The QT interval is the time between the beginning of the Q-wave and the end of the T-wave.
QTc	QTc represents the heart rate corrected QT interval. By default, the Information Center uses the Bazett correction formula to correct the QT interval for heart rate. Your system, however, may be set up to use the Fridericia correction formula.
dQTc	The difference between the current QTc value and the QTc baseline value.
QT-HR	The heart rate used to calculate QTc

**Note**—Turning QT analysis off does not clear the baseline value. This allows you to turn QT analysis off during prolonged arrhythmias, such as bigeminy, without losing the baseline.

## Limitations for QT Monitoring

Some conditions may make it difficult to achieve reliable QT monitoring. When this occurs the CANNOT ANALYZE QT INOP message displays at the Information Center, along with a QT STATUS message. Some conditions that may make reliable QT monitoring difficult include:

- **T-Wave Detection Limitations.**

Flat T-wave, atrial Fibrillation or atrial Flutter and prominent U-waves can make QT monitoring difficult. For these cases you should select **All** as the QT Lead on the QT window. The Information Center will use the lead or leads that have a T-wave with sufficient amplitude and can be detected. Alternatively select a single lead with a good T- wave amplitude and no visible flutter activity and without a predominant U-wave or P-wave.

- **QRS Changes**

QRS changes such as widened QRS can affect QT monitoring. If a long QTc is observed verify that is not caused by QRS widening.

- **Rhythm and Rate Limitations**

Rhythm and rate limitations such as high heart rate (> 150 beats/min for adult patients or > 180 beats/min for pediatric or neonatal patients), paced rhythm and bigeminy rhythm can make reliable QT monitoring difficult. If rhythm is sustained you may want to consider turning QT interval monitoring off.

QT Interval Monitoring

## 7. Monitoring Pulse Rate

This section provides an introduction to the Pulse measurement and its application.

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Displaying the Pulse Rate Measurement at the MX40.....	7-3

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## Pulse Rate Measurement

The pulse rate measurement counts the arterial pulsations that result from the mechanical activity of the heart in beats per minute (bpm). The pulse rate is derived from the SpO<sub>2</sub> measurement. Displayed results can range from 30 to 300 bpm. There is no alarm function for pulse rate.

The pulse numeric is displayed at the Information Center only when SpO<sub>2</sub> is being measured continuously. Manual measurements are displayed at the MX40 with a time stamp. There are no alarms associated with the pulse measurement. Pulse is turned on in the **Telemetry Setup** window at the IntelliVue Information Center Release N or earlier and using the **Measurements/SpO<sub>2</sub>** page at the IntelliVue Information Center iX.



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## Displaying the Pulse Rate Measurement at the MX40

➤ ***To display the pulse rate measurement at the MX40:***

- 1 If not already selected, press the Main Screen button and select the 1 waveform with 4 numerics display.
- 2 If pulse is not already displayed, touch a numeric.
- 3 Select **Change Numeric**.
- 4 Select **Pulse**.

Displaying the Pulse Rate Measurement at the MX40

## 8. Monitoring Respiration Rate (Resp)

This section provides an introduction to the Respiration Rate measurement and its application.

**Note** — Resp is only available with the IntelliVue Information Center iX.

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Resp Safety Information .....	8-3
Lead Placement for Monitoring Resp .....	8-4
Displaying Resp on the MX40 .....	8-5

---

## Respiration Rate Measurement

For the respiratory measurement (Resp), the MX40 measures the thoracic impedance between two ECG electrodes on the patient's chest. Changes in the impedance due to thoracic movement produce the Resp waveform on the display. The MX40 counts the waveform cycles to calculate the respiration rate (RR). The waveform size can be set using the **Setup Resp** menu which is displayed when you touch the Resp measurement area.

Settings for Resp On/Off, alarms, alarm limits and apnea time are defined at the Information Center. When the ECG measurement is turned off, the Resp measurement is also turned off.

**Note** — The Resp measurement is not available when the MX40 is wirelessly connected to MP5T, MP2, or X2 patient monitors. When not connected wirelessly to a monitor and Resp is being measured, the message **SRR Unavailable with Resp** is displayed on the MX40.

---

## Resp Safety Information

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### Warning

**Apnea** The respiration measurement does not recognize obstructive and mixed apneas. It only indicates an alarm when a pre-adjusted time has elapsed since the last detected breath.

**Resp Accessories** To monitor respiration, use only non-OR ECG accessories as listed in the Accessories Appendix.

**Rate Adaptive Pacemakers** Implanted pacemakers which can adapt to the Minute Ventilation rate may occasionally react on the Impedance measurement used by devices for the determination of the Resp value and execute pacing with the maximum programmed rate. Turning off the Resp measurement can prevent this.

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## Lead Placement for Monitoring Resp

Correct patient skin preparation techniques for electrode placement are important for Resp measurement. See Connecting and Positioning ECG Electrodes p. 6-6.

The Resp measurement uses the standard MX40 patient cable. You can use 3-wire, 5-wire, or 6-wire leadsets, using either Standard or EASI placement.

### Optimizing Lead Placement for Resp

If you want to measure Resp and you are already measuring ECG, you may need to optimize placement of the two electrodes between which Resp will be measured. Repositioning ECG electrodes from standard positions, especially when you are using EASI placement, results in changes in the ECG waveform and may influence ST and arrhythmia interpretation.

### Cardiac Overlay

Cardiac activity that affects the Resp waveform is called cardiac overlay. Cardiac overlay happens when the Resp electrodes pick up impedance changes caused by the rhythmic blood flow. Correct electrode placement can help to reduce cardiac overlay. Avoid the liver area and the ventricles of the heart in the line between the respiratory electrodes.

### Abdominal Breathing

Some patients with restricted chest movement breathe mainly abdominally. In these cases, you may need to place the left leg electrode on the left abdomen at the point of maximum abdominal expansion to optimize the respiratory wave.

---

## Displaying Resp on the MX40

➤ ***To display the Resp waveform and/or numeric:***

- 1 At the IntelliVue Information Center iX, select the **Measurements** button from the Main Window.
- 2 From the Measurements Window, select **Resp**.
- 3 Click the **I/O Resp** button to toggle on or off as appropriate.
- 4 At the MX40, select a waveform area to display the Resp waveform.
- 5 The **Change Wave** menu is displayed.
- 6 From the Change Wave menu, select **Resp**.
- 7 Select any measurement numeric to change to display the Resp numeric.
- 8 Select **Change Numeric** (it may be necessary to scroll down).

**Note** — The **Change Wave** menu is also used to adjust the Resp waveform size at the MX40 and at the IntelliVue Information Center iX.)

- 9 From the Change Numeric menu, select **Resp**.

Displaying Resp on the MX40



## 9. SpO<sub>2</sub> Monitoring

This section provides an introduction to the SpO<sub>2</sub> measurement and its application.

SpO <sub>2</sub> Safety Information .....	9-2
Pulse Oximetry Measurement .....	9-5

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## SpO<sub>2</sub> Safety Information

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### Warnings

- Always confirm monitor observations with clinical observation of the patient before administering interventions.
- Prolonged, continuous monitoring can increase the risk of changes in skin characteristics, such as irritation, reddening, blistering or pressure necrosis, particularly on patients with impaired perfusion and varying or immature skin morphology. Specific attention must be given to sensor site inspection for changes in skin quality, proper optical path alignment and attachment. Check the application site at regular intervals and change the site if any compromise in skin quality should occur. More frequent checking can be required due to an individual patient's condition.
- Injected dyes such as methylene blue or intravascular dyshemoglobins such as methemoglobin and carboxyhemoglobin can lead to inaccurate (over-estimated) measurements.
- Interference leading to inaccurate measurements can be caused by:
  - High levels of ambient light (Hint: cover application site with opaque material)
  - Electromagnetic interference
  - Excessive patient movement and vibration.
- This equipment is not suitable for use in the presence of a flammable anesthetic mixture or oxygen concentrations greater than 25% (or partial pressures greater than 27,5 kPa /206.27 mmHg).
- Disposable SpO<sub>2</sub> sensors can be damaged and lead to patient harm if they become wet. Wet sensors must be replaced immediately.
- To avoid venous pulsation, obstructed circulation, pressure marks, pressure necrosis, artifacts and inaccurate measurements, make sure that the sensor is not too tight. If the sensor is too tight, because the application site is too large or becomes too large due to edema, excessive pressure may be applied. This can result in venous congestion distal from the application site, leading to interstitial edema, hypoxia and tissue malnutrition.
- Inspect the sensor application site every 2 to 3 hours to ensure skin integrity, correct optical alignment, and circulation distal to the sensor site. Move the sensor application site every four hours, or more often if circulation or skin integrity is compromised.

- At elevated ambient temperatures, be careful with measurement sites that are not well perfused, because this can cause severe burns after prolonged application. All listed sensors operate without risk of exceeding 41° C on the skin if the initial skin temperature does not exceed 37° C.
  - Avoid placing the sensor on extremities with an arterial catheter or intravascular venous infusion line.
  - Sensors connected to the MX40 but not applied to the patient, can produce an error measurement. To avoid misdiagnosis, ensure the sensor is properly applied to the patient.
- 

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### Cautions

- If you measure SpO<sub>2</sub> on a limb that has an inflated NBP cuff, a non-pulsatile SpO<sub>2</sub> INOP (SpO<sub>2</sub>T NO PULSE) can occur. If the monitor is configured to suppress this alarm, there may be a delay of up to 60 seconds in indicating critical patient status, such as sudden pulse loss or hypoxia.
  - Do not use OxiCliq disposable sensors in a high humidity environment, such as an incubator, or in the presence of fluids, which may contaminate sensor and electrical connections causing unreliable or intermittent measurements. Do not use disposable sensors on patients who have allergic reactions to the adhesive.
  - When the MX40 is connected to a patient monitor using the MX40 / IntelliVue Patient Monitor Adapter Cable, (p/n 989803172211), the SpO<sub>2</sub> sensor must be directly connected to the patient monitor to monitor SpO<sub>2</sub>.
  - Do not use more than one extension cable (M1941A). See Appendix A, Accessories, for information on which sensors cannot be used with an extension cable.
  - Position the sensor cable away from power cables to avoid electrical interference.
- 

## SpO<sub>2</sub> Information for the User

The pulse oximeter is calibrated to indicate functional oxygen saturation (fractional oxyhemoglobin), and displayed results can range from 0 to 100%.

## SpO2 Safety Information

A 10 second averaging filter is used in the calculation of the result. Displayed results are typically updated every second, but the update period can be automatically delayed by up to 30 seconds in the presence of noise.

**Note** — The averaging filter time period is configurable at the IntelliVue Information Center iX (default = 10 seconds).

Physiological SpO<sub>2</sub> alarm signals will be generated. For adult patients, the SpO<sub>2</sub> low limit can be set between 50 and 99% inclusive, in 1% increments, and the SpO<sub>2</sub> high alarm limit can be set between 51 and 100% inclusive, in 1% increments. For pediatric patients, the SpO<sub>2</sub> low limit can be set between 30 and 99% inclusive, in 1% increments, and the high alarm limit can be set between 31 and 100% inclusive, in 1% increments. The maximum delay between the physiological alarm condition and alarm signal generation is 25 seconds.

Pulse rate is also derived from the pulsatile SpO<sub>2</sub> measurement, and displayed results can range from 30 to 300 bpm. There is no alarm function for pulse rate.

The pleth wave is auto-scaled to maximum display size. It decreases only when the signal quality becomes marginal. Pleth wave size is NOT directly proportional to the pulse volume.

---

## Pulse Oximetry Measurement

The MX40 supports an SpO<sub>2</sub> sensor connection using Fourier Artifact Suppression Technology (FAST). The FAST algorithm overcomes many of the issues associated with traditional pulse oximetry such as sensitivity to patient movement and intense ambient light. The algorithm offers improved motion artifact rejection as well as performance improvements for patients with low perfusion. SpO<sub>2</sub> can be measured continuously, where a value is sent to the Information Center every second, or as a single, individual Manual measurement. The Manual measurement will be removed from the Information Center display after 1 hour.

The SpO<sub>2</sub> parameter measures the arterial oxygen saturation, that is, the percentage of oxygenated hemoglobin in relation to the total hemoglobin.

If, for example, a total of 97% of the hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has an oxygen saturation of 97%. The SpO<sub>2</sub> numeric that appears on the monitor will read 97%. The SpO<sub>2</sub> numeric indicates the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin.

- The oxygen saturation is measured using the pulse oximetry method. This is a noninvasive method of measuring the arterial hemoglobin oxygen saturation. It measures how much light, sent from light sources on one side of the sensor, travels through patient tissue (such as a finger or an ear), to a receiver on the other side of the sensor.
- The amount of light passing through depends on many factors, most of which are constant, such as tissue or venous blood. However one of the factors, the blood flow in the arterioles, varies with time because it is pulsatile.

This measurement principle is used to derive the SpO<sub>2</sub> measurement. The numeric that is displayed is the oxygen saturation of the arterial blood - the measurement of light absorption during a pulsation. Correct placement of the sensor is essential for accurate measurements.

**Note**—Because pulse oximeter equipment measurements are statistically distributed, only about two-thirds of pulse oximeter equipment measurements can be expected to fall within  $\pm 1$  Arms of the value measured by a CO-oximeter.

## SpO<sub>2</sub> Sensors

Familiarize yourself with the instructions for use supplied with your sensor before using it. In particular, check that the sensor being used is appropriate for your patient category and application site. See Appendix A, Accessories, for a complete listing of supported sensors for the MX40.

## Selecting an SpO<sub>2</sub> Sensor

---

### Warning

- Use only Philips-approved accessories. Use of product accessories (patient cables, SpO<sub>2</sub> sensors, etc.) other than those specified in this manual may lead to patient injury or result in increased electromagnetic emissions or decreased immunity of the product.
  - Reuse: Never reuse disposable sensors, accessories and so forth that are intended for single use, or single patient use only.
  - Packaging: Do not use a sterilized accessory if the packaging is damaged.
  - Do not use disposable sensors on patients who exhibit allergic reactions to the adhesive.
  - When the specified Nellcor® sensors are used, the application must be consistent with the sensor manufacturer's own guidelines.
- 

Philips reusable sensors in adult, pediatric and infant (an alternative for use on adult patients only) models can be used, as well as Philips and Nellcor® disposable sensors.

---

### Caution

Do not use OxiCliq disposable sensors in a high humidity environment, or in the presence of fluids. These can contaminate sensor and electrical connections, and thereby cause unreliable or intermittent measurements.

The following table will help you in selecting the correct sensor type.

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Sensor Type	When to Use
<b>Reusable</b>	<p>You can use reusable sensors on different patients after cleaning and disinfecting them. For care and cleaning instructions, see the instructions accompanying the sensors. Reusable sensors should be changed to another site every four hours or in accordance with your clinical practice guidelines.</p> <p>See the Directions for Use supplied by Nellcor® Incorporated for instructions on preparation and application of reusable sensors.</p>
<b>Disposable</b>	<p>Use disposable sensors only once and then discard. However, you can relocate them to a different patient-site if the first location does not give the desired results. Do not reuse disposable sensors on different patients.</p> <p><b>Note</b> — See the Instructions for Use supplied by Nellcor® Incorporated for instructions on preparation and application of disposable sensors.</p>

## Sensor Application Safety Information

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### Warning

Failure to apply a sensor properly can reduce the accuracy of the SpO<sub>2</sub> measurement.

- **Loose/Tight sensor:** If a sensor is too loose, it can compromise the optical alignment or fall off. If it is too tight, for example because the application site is too large or becomes too large due to edema, excessive pressure can be applied. This can result in venous congestion distal from the application site, leading to interstitial edema, hypoxia and tissue malnutrition.
- **Skin irritations or ulcerations** can occur as a result of the sensor being attached to one location for too long. To avoid skin irritations and ulcerations, inspect the sensor application site every 2-3 hours, and change the application site at least every 4 hours or according to clinical practice guidelines.
- **Venous Pulsation:** Do not apply sensor too tightly as this results in venous pulsation, which can severely obstruct circulation and lead to inaccurate measurements.

## Pulse Oximetry Measurement

- **Ambient Temperature:** Never apply an SpO<sub>2</sub> sensor at ambient temperatures above 37 °C (99 °F) because this can cause severe burns after prolonged application.
  - **Extremities to Avoid:** Avoid sites distal to NBP cuff, intra-arterial line, or intravascular venous infusion line.
- 

## Applying the Sensor

- 1 Follow the SpO<sub>2</sub> sensor's Instructions for Use, adhering to all warnings and cautions.
- 2 If necessary, remove colored nail polish from the application site.
- 3 Apply the sensor to the patient. The application site should match the sensor size so that the sensor can neither fall off, nor apply excessive pressure.
- 4 Check that the light emitter and the photodetector are directly opposite each other. All light from the emitter must pass through the patient's tissue.

## Connecting SpO<sub>2</sub> Cables

The sensor cable is either directly connected to the blue SpO<sub>2</sub> connector on the MX40 patient cable or is connected to an adapter cable that is then connected to the MX40 SpO<sub>2</sub> connector.

## Tone Modulation Indication

The pulse signal tone is controlled by the setting in the **SpO<sub>2</sub> Tone Modulation** menu.

**Note** — Tone Modulation Indication is only available when operating in Continuous mode. It is not available when operating in Manual or Auto mode.

## Signal Quality Indicator

The SpO<sub>2</sub> numeric is displayed together with a signal quality indicator which gives an indication of the reliability of the current values.

The level to which the triangle is filled shows the quality of the signal. The signal quality is at a maximum when the triangle is completely filled.



## Measuring SpO<sub>2</sub>

---

### Warning

- Removal of the SpO<sub>2</sub> sensor from the MX40 patient cable during Continuous SpO<sub>2</sub> monitoring results in a "No Sensor" technical alarm. Silencing this alarm turns the SpO<sub>2</sub> measurement off, however the SpO<sub>2</sub> module is still operating in the background and consuming battery power. If you do not intend to resume continuous SpO<sub>2</sub> monitoring, change to Manual mode. There is no technical alarm for a "No Sensor" condition in Manual mode.
  - If you measure SpO<sub>2</sub> on a limb that has an inflated NBP cuff, a non-pulsatile SpO<sub>2</sub> technical alarm can occur. If the monitor is configured to suppress this alarm, there can be a delay of up to 60 seconds in indicating critical patient status, such as hypoxia.
- 

SpO<sub>2</sub> measurements can be made manually on an as-needed basis in Manual mode, continuously in Continuous mode, or automatically in Auto mode (IntelliVue Information Center iX only), depending on your MX40 configuration. While operating in Continuous mode, you can also measure pulse, and display the pleth wave on the MX40 and at the Information Center. The SpO<sub>2</sub> parameter is turned on/off at the MX40 or by a control from the Information Center. SpO<sub>2</sub> monitoring consumes considerable electrical energy. The battery power must be at least 10% full in order to make SpO<sub>2</sub> measurements.

To resume the SpO<sub>2</sub> measurement after it has been turned off, touch the blank measurement area and select **SpO<sub>2</sub>** to turn it back on.

**Note** — Before disabling SpO<sub>2</sub> at the Information Center, acknowledge any active alarms at the MX40.

Setting the SpO<sub>2</sub> mode can be done at the Information Center or at the MX40.

### ➤ **To select the measurement mode at the MX40:**

- 1 In **SpO<sub>2</sub> Setup**, select **Mode**.
- 2 Select **Continuous**, **Manual** or **Auto** mode.

## Understanding SpO<sub>2</sub> Alarms

SpO<sub>2</sub> monitoring offers high and low limit alarms, and a high priority (red level) oxygen desaturation alarm. For adult patients, the SpO<sub>2</sub> low limit can be set between 50 and 99% inclusive, in 1% increments. For pediatric patients, the SpO<sub>2</sub> low limit can be set between 30 and 99% inclusive, in 1% increments. You cannot set the low limit below the desaturation limit. The SpO<sub>2</sub> high alarm limit can be set between 51 and 100% inclusive, in 1% increments for adult patients and set for pediatric patients between 31 and 100% inclusive, in 1% increments.

The delay between the physiologic alarm condition and alarm annunciation at the MX40 is <16 seconds. This means that the MX40 will generate an alarm if the averaged numeric value on the display exists beyond the alarm limit for more than a maximum of 16 seconds.

Setting the high SpO<sub>2</sub> alarm limit to 100% is equivalent to switching off the high alarm. Therefore the upper alarm limit for oxygen saturation must be carefully selected in accordance with accepted clinical practices.

The default setting for SpO<sub>2</sub> yellow alarms is latched. That is, when an SpO<sub>2</sub> limit is exceeded, you will need to acknowledge it at the Information Center. The sound will be silenced but the message will remain on the display until the condition is resolved.


## 10. Monitoring with other Assigned Devices

This section provides information about the use of the MX40 when it is assigned to other monitoring devices. The MX40 can be assigned to IntelliVue Patient Monitors or IntelliVue Cableless Measurements for SpO<sub>2</sub> and NBP. The connection to these other devices is done by pairing networked devices or using the integrated short-range radio of the MX40.

For additional information on IntelliVue Patient Monitor or IntelliVue Cableless Measurements operation, consult the Instructions for Use that accompanied the device.

---

### Warning

Assignment of the MX40 to IntelliVue Patient Monitors is only supported when the patient monitor (MP5,MP5T,MP5SC, MP2 or X2 only) is equipped with a short-range radio. Monitors that have this equipment will display the short-range radio symbol  on the label.

---

### Caution

When the MX40 is connected to a patient monitor using the MX40 / IntelliVue Patient Monitor Adapter Cable, (p/n 989803172211), the SpO<sub>2</sub> sensor must be directly connected to the patient monitor to monitor SpO<sub>2</sub>.

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**Note** — Assignment of the MX40 to IntelliVue Patient Monitors is not available with patient monitors connected to the M3140 Information Center.

**Note** — The MP5T and MP5SC are non-networked devices as they does not support a connection to the Information Center.

## Pulse Oximetry Measurement

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## Assigning Devices

### Device Assignment at the Information Center

You can assign an MX40 to a patient monitor at the Information Center. The data from the MX40 automatically displays as a permanent overview session in the **Telemetry Data** window on the patient monitor.

At the Information Center the MX40 data and the patient monitor data are integrated in the patient sector.

---

#### Warning

All data presented in the Telemetry Data window are delayed for several seconds. If you need realtime data, e.g. for defibrillation, always use the ECG from the patient monitor.

---


### Device Assignment at the MX40

➤ ***To assign an MX40 to an IntelliVue Cableless Measurement device:***


- 1 Press the SmartKey button.
- 2 Press the **Add/Remove** SmartKey.
- 3 From the **Add to** menu, select the desired device and press **Confirm**.

The MX40 will attempt to complete the assignment for a 2-minute period. If assignment fails or the MX40 is no longer in range of the other device, the short-range radio turns off to save battery power. Repeat the procedure above to retry or resume the assignment. You may also need to restart the short-range radio at the cableless measurement device if it has entered its power save mode. Touch and hold the left button on the device to restart the short-range radio.

➤ ***To assign an MX40 to an IntelliVue Patient Monitor:***

- 1 Press the SmartKey button.
- 2 Press the **Add/Remove** SmartKey. The measurement selection key on the monitor will change to show the "add cableless" icon .
- 3 In the **Add Cableless** menu, select the correct equipment label for the device.

## Assigning Devices

When connected the  icon appears at the Information Center, Release N or earlier.

The MX40 is assigned to the monitor. A "Tele Device Assigned" message appears on the monitor. If the ECG wave now appears on the monitor, the signal from the MX40 is successfully transmitting to the monitor. To confirm that the correct MX40 has been assigned, open the ECG Setup menu by touching the ECG waveform or HR numeric. The title of the menu contains the equipment label of the MX40. Check that this is the correct label.

When assigned to the monitor, the display of the MX40 appears as shown below:



The display is primarily inactive, and there is no viewable patient data displayed, however, battery status information is available.

If a monitor is already paired to another device, you cannot assign an MX40 to that monitor.

If the MX40 goes out-of-range or loses the short-range radio connection, it will switch over to standard telemetry transmission to the Information Center. In this case, the telemetry data is displayed in the Telemetry Data Window.

If the devices are unassigned, the short-range radio connection is ended

### ➤ ***To remove an assigned device from the MX40:***

- 1 Press the SmartKey button.
- 2 Press the **Add/Remove** SmartKey.
- 3 From the **Remove from** menu, select the desired device and press **Confirm**.

## Device Assignment at the Patient Monitor

At the patient monitor, you can assign an MX40 to the patient monitor using the **Telemetry** menu on the patient monitor.

When the devices are networked, all data is sent to the Information Center. When non-networked, only the additional parameters measured at the patient monitor (NBP, SpO<sub>2</sub>, and predictive temperature) are sent to the Information Center. The **Telemetry Data** window is not displayed when devices are non-networked.

Controls Available when Assigned to IntelliVue Cableless Measurements

## Controls Available when Assigned to IntelliVue Cableless Measurements

Action	At the MX40	At the Cableless Measurement Device	At the IIC	At the IIC iX
<b>SpO<sub>2</sub></b>				
Start SpO <sub>2</sub>	Yes	Yes	Yes	Yes
Change SpO <sub>2</sub> Mode	Yes	Yes	Yes	Yes
Select SpO <sub>2</sub> Repetition Time	No	Yes	No	Yes
Assign SpO <sub>2</sub> Pod	Yes	Yes	No	No
Remove SpO <sub>2</sub> Pod	Yes	Yes	Yes	No
Change Alarm Limits	No	No	Yes	Yes
Place Device in Standby	Yes	No	No	Yes
Alarm Silence	Yes (local only)	No	Yes	Yes
Alarm Off/Pause	Yes (if enabled)	No	Yes	Yes
<b>NBP</b>				
Start/Stop/Stat NBP	Yes	Yes	Yes	Yes
Change NBP Mode	Yes	Yes	No	No
Change NBP Repetition Time	No	Yes	No	No
Change Alarm Limits	No	No	Yes	Yes
Assign NBP Pod	Yes	Yes	No	No
Remove NBP Pod	Yes	Yes	Yes	No
Place Device in Standby	Yes	No	No	Yes
Alarm Silence	Yes (local only)	No	Yes	Yes
Alarm Off/Pause	Yes (if enabled)	No	Yes	Yes



## Controls Available when Assigned to IntelliVue Patient Monitors

Action	At the MX40 (N/A)	At the Patient Monitor	At the IIC	At the IIC iX
<b>SpO<sub>2</sub></b>				
Start SpO <sub>2</sub>		Yes	Yes	Yes
Change SpO <sub>2</sub> Mode		Yes	Yes	Yes
Select SpO <sub>2</sub> Repetition Time		Yes	No	Yes
Assign SpO <sub>2</sub> Pod		Yes	No	No
Remove SpO <sub>2</sub> Pod		Yes	Yes	No
Change Alarm Limits		Yes	Yes	Yes
Place Device in Standby		No	No	Yes
Alarm Silence		Yes	Yes	Yes
Alarm Off/Pause		Yes	No	Yes
<b>NBP</b>				
Start/Stop/Stat NBP		Yes	Yes	Yes
Change NBP Mode		Yes	No	No
Change NBP Repetition Time		Yes	No	Yes
Change Alarm Limits		Yes	Yes	Yes
Assign NBP Pod		Yes	No	No
Remove NBP Pod		Yes	Yes	No
Place Device in Standby		No	No	Yes
Alarm Silence		Yes	Yes	Yes
Alarm Off/Pause		Yes	No	Yes

## Networked Device Synchronized Settings

If the patient's ECG is initially being measured with a patient monitor, and then the patient is connected to the MX40 for monitoring, the Information Center will use the patient monitor settings for the MX40. When the initial ECG source is the MX40, and then the patient is connected to the monitor, the Information Center uses its Telemetry Setup settings. The following settings will be synchronized:

<b>Heart Rate</b>	HR/Pulse Alarm On/Off, Heart Rate High/Low Limit
<b>ECG</b>	Primary Lead, Secondary Lead, Va Lead, Vb Lead
<b>Arrhythmia</b>	On/Unlocked, On/Locked, Off/Unlocked, Off/Locked, Off/Not Available, Analysis Mode, Asystole Threshold, Pause Threshold, VTach HR, VTach Run, PVCs/min, Vent. Rhythm, SVT HR, SVT Run, PVCs/min On/Off, Pacer not Capture On/Off, Pacer not Pace On/Off, Non-sustain On/Off, Vent. Rhythm On/Off, Run PVCs On/Off, Pair PVCs On/Off, Missed Beat On/Off, Pause On/Off, R-on-T On/Off, Vent. Bigeminy On/Off, Vent. Trigeminy On/Off, Multiform PVCs On/Off, Irregular HR On/Off, SVT On/Off, Afib On/Off, End Afib Time, Afib Remind Time
<b>ST</b>	ST Analysis On/Off, ST Alarm On/Off, ISO point, J point, ST point, ST Priority List, Single ST Alarm Limit, Multi ST Alarm Limit, ST Auto/Manual
<b>STE</b>	STE Analysis On/Off, STE Alarm On/Off
<b>QT</b>	QT Analysis On/Off, QTc High On/Off, QTc High Alarm Limit, dQTc High On/Off, dQTc High Alarm Limit, QT Lead, QTc Correction Formula, QT Baseline
<b>SpO<sub>2</sub>T</b>	SpO <sub>2</sub> Alarms On/Off, SpO <sub>2</sub> Alarm Limits, NBP Alarm Suppression On/Off, Pulse (SpO <sub>2</sub> ) On/Off, Desat Limit, SpO <sub>2</sub> Averaging Time

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## MX40 Display when Wirelessly Connected to a Patient Monitor

When the MX40 is wirelessly connected to a patient monitor via the short-range radio, its display is primarily inactive. There is no viewable patient data on the display, however, battery status information is available if the display is turned on.



MX40 Display when Wirelessly Connected to a Patient Monitor

# 11. Monitoring with the MX40 at the Information Center

This section describes the behavior of the MX40 as it relates to what is displayed at the Information Center. What is displayed depends on which version of the Information Center is in use, IntelliVue Information Center Release N or earlier (referred to here as IIC), or IntelliVue Information Center iX (referred here to as IIC iX).

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## MX40 Connection to the Information Center

Once the MX40 has been assigned to a sector at the Information Center, the settings (alarms, arrhythmia and configured Unit settings) are synchronized with the MX40. You may see a "Settings sync'd" message in the Status Area on connection, re-connection, and anytime the settings are updated at the Information Center. Arrhythmia Learning/Relearn occurs on connection and re-connection to the IIC.

---

### Warning

Since Relearn happens automatically at the IIC, if learning takes place during ventricular rhythm, the ectopics can be incorrectly learned as the normal QRS complex. This can result in missed detection of subsequent events of V-Tach and V-Fib. For this reason, you should:

- 1 Respond promptly to any technical alarm.
  - 2 Ensure that the arrhythmia algorithm is labeling beats correctly.
- 

Upon loss of connection to the Information Center the MX40:

- turns on its display
- displays the "NO CENTRAL MONIT" INOP
- uses the last known settings from the Information Center.
- new physiological alarms are announced locally only.
- Active alarms that occurred prior to the loss of connection can be viewed in the Alarm List.

When a loss of battery power occurs while not connected to the Information Center, the MX40 retains the last known alarm limits and vitals trends data but this is not sent to the Information Center at re-connection. Patient name is restored at re-connection.

When operating wirelessly via a short-range radio connection to an IntelliVue Patient Monitor, changes made to patient name are updated at the Information Center and the patient monitor, however, they are not reflected in the Patient Information Area on the MX40. The update occurs when network connection is restored.

---

## MX40 Controls in the Patient Window (IIC)

The Patient Window at the Information Center (accessed from the Patient Window control in the Patient Sector) includes controls for a number of MX40 operations. For detailed instructions on these operations, see the *IntelliVue Information Center Instructions for Use* or the *Online Help*.

➤ **To View ECG or SpO<sub>2</sub> Alarm Limits**

- 1 Move the cursor over the **HR** or **SpO<sub>2</sub>** label to display the current high and low alarm limits.

➤ **To Change ECG or SpO<sub>2</sub> Alarm Limits**

- 1 Move the cursor over the High or Low numeric to display up/down arrow controls for adjusting the limit.
- 2 After adjusting the limit, move the cursor away from the area to dismiss the limit controls.

➤ **To Change ECG Waveform Size**

- 1 Move the cursor over the ECG waveform to display the **ECG Waveform Size** control.
- 2 Select the desired size from the list.

➤ **To Select Lead**

- 1 Move the cursor over the ECG waveform to display the Lead Selection control.
- 2 Select the desired lead from the list.

**Important** — Do not set the primary and secondary channels to the same lead.

➤ **To Change Va and Vb Default Lead Settings (6-lead only)**

- 1 Move the cursor over the ECG waveform to display the **Lead Selection** popup.
- 2 Select the label from the label list.
- 3 For Va or Vb, select Va or Vb, then select the lead to be assigned. Assignment of the same V lead to both Va and Vb is not allowed.

**Important** — Do not set the primary and secondary channels to the same lead.

MX40 Controls in the Patient Window (IIC)

➤ ***To Initiate a Spot Check (Manual) Spo<sub>2</sub> Measurement***

- 1 Move the cursor over the SpO<sub>2</sub> label.
- 2 Click on the Spot Check (Manual) icon.





---

## MX40 Controls in the Patient Window (IIC iX)

The Patient Window at the Information Center iX includes controls for a number of MX40 operations. For detailed instructions on these operations, see the *IntelliVue Information Center iX Instructions for Use* or the *Online Help*.

➤ **To View ECG, Resp, NBP or SpO<sub>2</sub> Alarm Limits**

- 1 Click on the **HR** or **SpO<sub>2</sub>** label in the Patient Window to display the current high and low alarm limits.

➤ **To Change ECG, Resp, NBP or SpO<sub>2</sub> Alarm Limits**

- 1 Click on the **HR** or **SpO<sub>2</sub>** label in the Patient Window.
- 2 Click on **High Limit** or **Low Limit** and select the new value from the list.

➤ **To Change Paced Status**

- 1 Click on the **HR** label in the Patient Window.
- 2 Click on **Paced Mode**.
- 3 Click on **Off** or **On** to select the status.

---

### Warning

At admission/discharge, always check that paced status is correct for the patient.

---

➤ **To Change ECG Waveform Size**

- 1 Click on the appropriate waveform.
- 2 Select **Size Up** or **Size Down**.

➤ **To Select Lead**

- 1 Click the appropriate waveform.
- 2 Select the desired lead label from the list.

**Important** — Do not set the primary and secondary channels to the same lead.

➤ **To Change Va and Vb Default Lead Settings (6-lead only)**

- 1 Click the **Measurements Application** button.
- 2 Select **ECG** from the menu on the left.
- 3 Select **Va** or **Vb** from the **ECG** menu on the right and select from the list.

MX40 Controls in the Patient Window (IIC iX)

➤ ***To Initiate a Manual SpO<sub>2</sub> Measurement***

- 1 Click the **Measurements Application** button.
- 2 Select **SpO<sub>2</sub>** from the menu on the left.
- 3 Select **Start** from the **SpO<sub>2</sub>** menu on the right.

---

## Locating the MX40 (Find Device)

The Find Device feature enables you to generate an alternating pitch repeated tone at the MX40 to assist in locating a missing device. Find Device requires that the MX40 has sufficient battery power and is within the coverage area.

➤ ***To locate an MX40 (IIC):***

- 1 From the Patient Window, select **Telemetry Setup**.
- 2 Select **Find Device** to generate a repeated tone at the MX40.  
To silence this tone, touch the silence key on the MX40.

➤ ***To locate an MX40 (IIC iX):***

- 1 Click the **Measurements** application button.
  - 2 Select **Telemetry Setup**.
  - 3 Select **Find**.
- To silence this tone, touch the silence key on the MX40.

---

## Viewing Device Location and Location History (optional)

MX40 Device Location information is identified in the Patient Window by a compass icon followed by the location name of the access point that the MX40 is currently connected to. If the location of the device changes, the Patient Window is updated within 5 seconds of the location change.

### Location History (IIC)

You can view the location history for a particular MX40 in the Device Location History field in the Telemetry Setup window. The field displays the five most recent Device Location descriptions in ascending order. The total timespan of the log is 60 minutes.

### Location History (IIC iX)

You can view the location history for a particular MX40 by clicking on the compass icon in the Patient Window. The location and time-stamped history is displayed for each equipment label.

---

### Warning

Because the coverage range of Access Points can sometimes overlap, including different floor levels, the IntelliVue Device Location feature is not intended for use when attempting to locate a patient.

---

**Note** — If there is a change in location while viewing the history in the Telemetry Setup window, you must re-enter Telemetry Setup to see the change, as it does not update automatically.

**Note** — The IntelliVue Device Location feature is not supported for use with the MX40 WLAN device, Part Number 865352.

---

## Using the Device Location Client (optional - IIC only)

The Device Location Client application is an optional software application that allows you to display and locate devices visually, using Floor Plans associated with your hospital's layout. Device location history is also available. The application is accessible using a separate PC's web browser. For additional installation information, see the *IntelliVue Device Location Installation Guide*.

---

### Warning

Because the coverage range of Access Points can sometimes overlap, including different floor levels, the IntelliVue Device Location feature is not intended for use when attempting to locate a patient.

---

### Displaying and Locating Devices

The left side of the Client display screen contains a list of clinical units associated with the current Floor Plan. Each unit contains a list of bed labels. You view the beds listed within a unit by clicking on the plus sign next to the unit name.

**Note** — The beds listed are only those equipped with traditional IntelliVue telemetry devices or the MX40.

To identify and locate the device associated with the bed, simply click on the desired bed label. The floor plan and the status bar above the floor plan image now display the location of the device. Additionally, the status bar lists the Access Point the device is currently associated with.

### Viewing Device Location History

The location history of a particular device is also available. Select a device from the Device List box and then click on the down arrow in the status bar. The last five known locations of the device are displayed.

---

## **Patient Configurable Settings in Telemetry Setup (IIC)**

The Telemetry Setup window enables you to configure the MX40 for patient-specific settings. All patient-specific settings will be reset to the unit defaults upon patient discharge. To access the window, from the Patient Window click Telemetry Setup.

The following settings can be adjusted in this window:

## Patient Configurable Settings in Telemetry Setup (IIC)

Patient-Configurable Settings in Telemetry Setup			
Control	Function	Setting Choices	Factory Default
<b>Telemetry/ Multi-Function Button</b>	Determines the Information Center response when the Multi-Function Button is pressed.	<i>Nurse Call</i> - generate nurse call alarm that can be retrieved from Alarm Review for later use. <i>Record</i> - generate a recording strip <i>Nurse Call and Record</i> - generate nurse call alarm and recording strip <i>None</i>	Nurse Call
<b>Fixed Pacer Amplitude</b>	Sets the appearance of the pacer spikes to a fixed size as they appear in the patient window.	<i>enable</i> <i>disable</i> <b>Note</b> — this does not affect the appearance of the pacer spikes on the MX40.	disable
<b>SpO<sub>2</sub> Enabled</b>	Enable/disable the SpO <sub>2</sub> measurement at the Information Center and the MX40.	<i>enable</i> <i>disable</i>	enable
<b>SpO<sub>2</sub> Mode</b>	Determine the MX40 SpO <sub>2</sub> measurement behavior. <b>Note</b> — Pulse Rate and Pleth Wave are not available in Spot Check (Manual) mode.	<i>Spot Check (Manual)</i> - Provides manual measurements so the clinician can check as needed. Measurement can be initiated at the MX40 from the SmartKeys menu or the SpO <sub>2</sub> Setup menu and at the Information Center by selecting the Spot Check SpO <sub>2</sub> icon in the Patient Window.  <i>Continuous</i> - Sends an SpO <sub>2</sub> parameter value to the Information Center every second. If selected, Pulse Rate and Pleth Wave may also be sent.	Spot Check (Manual)

## Patient Configurable Settings in Telemetry Setup (IIC)

Patient-Configurable Settings in Telemetry Setup			
Control	Function	Setting Choices	Factory Default
<b>Suppress SpO<sub>2</sub> INOPs with NBP</b>	<p>Enable/disable the SpO<sub>2</sub> algorithm to suppress sending technical alarms from the MX40 during an NBP measurement for 60 seconds.</p> <hr/> <p><b>Warning</b></p> <p>If you measure SpO<sub>2</sub> on a limb that has an inflated NBP cuff, a non-pulsatile SpO<sub>2</sub> technical alarm can occur. If the monitor is configured to suppress this alarm, there can be a delay of up to 60 seconds in indicating critical patient status, such as sudden pulse loss or hypoxia.</p> <hr/>	<p><i>enable</i></p> <p><i>disable</i></p>	enable
<b>Pleth Wave</b>	<p>Enable/disable the transmission of the Pleth wave (and its subsequent display) to the Information Center. For Continuous SpO<sub>2</sub> mode only.</p>	<p><i>enable</i></p> <p><i>disable</i></p> <p><b>Note</b> — When enabled, the Pleth wave replaces the Vb wave in the Patient Window during 6-lead monitoring.</p>	disable (Pleth is not displayed.)
<b>Pulse</b>	<p>Enable/disable display of the Pulse rate at the Information Center. For Continuous SpO<sub>2</sub> mode only.</p>	<p><i>enable</i></p> <p><i>disable</i></p>	disable (Pulse rate is not displayed.)
<b>SpO<sub>2</sub> Alarm</b>	<p>Turn SpO<sub>2</sub> alarms on/off at the Information Center and the MX40.</p>	<p><i>enable</i> (on)</p> <p><i>disable</i> (off)</p>	enable
<b>Unit Settings</b>	<p>Change current settings back to last saved clinical unit settings.</p>	(none)	



---

## Unit Configurable Settings (IIC)

Unit Settings provide access to clinical configuration items that affect all patients on an Information Center. Changes in unit settings take effect upon discharge, except for Standby duration and SpO<sub>2</sub> mode, which take effect immediately.

Access to unit settings requires a password, and the displays are in English. Telemetry specific settings are accessed through All Controls -> Unit Settings -> Telemetry Setup. The setting for telemetry non-arrhythmia yellow alarms and INOP severity is located in All Controls -> Unit Settings -> Alarms. For all other information on unit settings, see *IntelliVue Information Center Instructions for Use*.

## Unit Configurable Settings (IIC)

Unit Settings - Telemetry Setup			
Control	Function	Settings	Factory Default
<b>Patient Type</b>	Set patient type used for SpO <sub>2</sub> alarm limits.	<i>Adult</i> <i>Pediatric</i>	Adult
<b>Telemetry/ Multi-Function Button</b>	Determine the Information Center response when Telemetry Button is pressed.	<i>Nurse Call</i> - generate nurse call alarm that can be retrieved from Alarm Review for later use. <i>Record</i> - generate a recording strip <i>Both</i> - generate nurse call alarm and recording strip <i>None</i>	Nurse Call
<b>Standby Duration</b>	Sets the standby duration on the MX40 when Standby is initiated from the Information Center.  <b>Note</b> — When Standby is initiated from the MX40, the duration is always Infinite.	<i>Infinite</i> <i>10 minutes</i> <i>20 minutes</i> <i>30 minutes</i> <i>1 hour</i> <i>2 hours</i> <i>3 hours</i> <i>4 hours</i>	Infinite
<b>Enable Remote Suspend</b>	Enable/disable alarm pause/suspend at the MX40.	<i>enable</i> <i>disable</i>	disable
<b>Suspend Duration</b>	Sets the alarm suspend duration time for each assigned device on the Information Center.	<i>1, 2, or 3 minutes</i>	2 minutes
<b>Battery Gauge on Information Center</b>	Display/disable a battery gauge for each assigned device on the Information Center.	<i>enable</i> <i>disable</i>	enable (battery gauge is displayed)  <b>Note</b> — the battery gauge is always displayed on the MX40.

Unit Settings - Telemetry Setup			
Control	Function	Settings	Factory Default
<b>RF Auto Shutoff</b>	Enable/disable RF operation during an extended situation of all leads off for more than 10 minutes and the SpO <sub>2</sub> is not being measured continuously.	<i>enable</i> <i>disable</i>	enable (MX40 will shut off after 10 minutes of Leads Off condition and SpO <sub>2</sub> is not being measured continuously. Reconnect the patient cable to resume monitoring.)
<b>Autopair</b>	Enable/disable the autopairing of the MX40 and the IntelliVue Patient Monitor at the Information Center.	<i>enable</i> <i>disable</i>	enable
<b>Enable Cableless Measurements</b>	Enable/disable the use of IntelliVue Cableless Measurements for SpO <sub>2</sub> and NBP	<i>enable</i> <i>disable</i>	disable
<b>SRR Fast Transition</b>	Reduce the delay time when fast switching between the MX40 and the patient monitor.	<i>enable</i> <i>disable</i>	enable
<b>Fixed Pacer Amplitude</b>	Sets the appearance of the pacer spikes at the Information Center to a fixed size as they appear in the patient window.	<i>enable</i> <i>disable</i>	disable
<b>Enable SpO<sub>2</sub></b>	Enable/disable the SpO <sub>2</sub> measurement at the Information Center.	<i>enable</i> <i>disable</i>	enable

## Unit Configurable Settings (IIC)

Unit Settings - Telemetry Setup			
Control	Function	Settings	Factory Default
<b>SpO<sub>2</sub> Mode</b>	<p>Determine the MX40 SpO<sub>2</sub> measurement behavior.</p> <p><b>Note</b> — Pulse Rate and Pleth Wave are not available in Spot Check (Manual) mode.</p>	<p><i>Spot Check (Manual)</i>- Provides manual measurements so the clinician can check as needed. Measurement can be initiated from the SmartKeys menu, the SpO<sub>2</sub> Setup menu or by selecting the Spot Check SpO<sub>2</sub> icon in the Patient Window.</p> <p><i>Continuous</i> - Sends an SpO<sub>2</sub> parameter value to the Information Center every second. If selected, Pulse Rate and Pleth Wave may also be sent.</p>	Spot Check (Manual)
<b>Suppress SpO<sub>2</sub> Inops with NBP</b>	<p>Enable/disable the SpO<sub>2</sub> algorithm to detect NBP running and suppress sending technical alarms from the MX40 for 60 seconds.</p> <hr/> <p><b>Warning</b></p> <p>If you measure SpO<sub>2</sub> on a limb that has an inflated NBP cuff, a non-pulsatile SpO<sub>2</sub> technical alarm can occur. If the monitor is configured to suppress this alarm, there can be a delay of up to 60 seconds in indicating critical patient status, such as sudden hypoxia.</p> <hr/>	<p><i>enable</i></p> <p><i>disable</i></p>	enable

Unit Settings - Telemetry Setup			
Control	Function	Settings	Factory Default
<b>Pleth Wave</b>	Enable/disable the transmission of the Pleth wave and its subsequent display to the Information Center. For Continuous mode only.	<i>enable</i> <i>disable</i> <b>Note</b> — When enabled, during 6-lead monitoring, the Pleth wave will replace the Vb wave in the Patient Window.	disable (Pleth wave is not displayed.)
<b>Pulse</b>	Enable/disable the transmission of the Pulse rate and its subsequent display to the Information Center. For Continuous mode only.	<i>enable</i> <i>disable</i>	disable (Pulse rate is not displayed.)
<b>SpO<sub>2</sub> Alarm</b>	Turn SpO <sub>2</sub> alarms on/off at the Information Center.	<i>enable</i> (on) <i>disable</i> (off)	enable
<b>SpO<sub>2</sub> Limits High</b>	Increment/decrement SpO <sub>2</sub> high alarm limit by 1 (in %).	Limit maximum is 100. Limit minimum is 51 (adult) or 31 (pediatric). High and low limit must be at least 1% apart.	100 (adult, pediatric)
<b>SpO<sub>2</sub> Limits Low</b>	Increment/decrement SpO <sub>2</sub> low alarm limit by 1 (in %).	Limit maximum is 99. Limit minimum is 50 (adult) or 30 (pediatric). High and low limit must be at least 1% apart.	90 (adult, pediatric)

## Unit Configurable Settings (IIC)

Unit Settings - Default Leads			
Control	Function	Settings	Factory Default
<b>3-wire</b>	Set the unit default lead.	<i>I, II, III</i>	II
<b>5-wire, ECG1</b>	Set the unit default lead.	<i>I, II, III, MCL, AVR, AVL, AVF, V</i>	II
<b>5-wire, ECG2</b>	Set the unit default lead.	<i>I, II, III, MCL, AVR, AVL, AVF, V</i>	V
<b>5-wire, ECG3</b>	Set the unit default lead.	<i>I, II, III, MCL, AVR, AVL, AVF, V</i>	III
<b>5-wire EASI, ECG1</b>	Set the unit default lead.	<i>I, II, III, AVR, AVL, AVF, V<sub>1</sub>, V<sub>2</sub>, V<sub>3</sub>, V<sub>4</sub>, V<sub>5</sub>, V<sub>6</sub></i>	II
<b>5-wire EASI, ECG2</b>	Set the unit default lead.	<i>I, II, III, AVR, AVL, AVF, V<sub>1</sub>, V<sub>2</sub>, V<sub>3</sub>, V<sub>4</sub>, V<sub>5</sub>, V<sub>6</sub></i>	V <sub>2</sub>
<b>5-wire EASI, ECG3</b>	Set the unit default lead.	<i>I, II, III, AVR, AVL, AVF, V<sub>1</sub>, V<sub>2</sub>, V<sub>3</sub>, V<sub>4</sub>, V<sub>5</sub>, V<sub>6</sub></i>	III
<b>5-wire EASI, ECG4</b>	Set the unit default lead.	<i>I, II, III, AVR, AVL, AVF, V<sub>1</sub>, V<sub>2</sub>, V<sub>3</sub>, V<sub>4</sub>, V<sub>5</sub>, V<sub>6</sub></i>	V <sub>5</sub>
<b>6-wire, Va</b>	Set the unit default lead	<i>V<sub>1</sub>, V<sub>2</sub>, V<sub>3</sub>, V<sub>4</sub>, V<sub>5</sub>, V<sub>6</sub>, V<sub>7</sub>, V<sub>8</sub>, V<sub>9</sub>, V<sub>3R</sub>, V<sub>4R</sub>, V<sub>5R</sub></i>	V <sub>2</sub>
<b>6-wire, Vb</b>	Set the unit default lead	<i>V<sub>1</sub>, V<sub>2</sub>, V<sub>3</sub>, V<sub>4</sub>, V<sub>5</sub>, V<sub>6</sub>, V<sub>7</sub>, V<sub>8</sub>, V<sub>9</sub>, V<sub>3R</sub>, V<sub>4R</sub>, V<sub>5R</sub></i>	V <sub>5</sub>
<b>6-wire, ECG1</b>	Set the unit default lead.	<i>I, II, III, MCL, AVR, AVL, AVF, V<sub>1</sub>, V<sub>2</sub>, V<sub>3</sub>, V<sub>4</sub>, V<sub>5</sub>, V<sub>6</sub>, V<sub>7</sub>, V<sub>8</sub>, V<sub>9</sub>, V<sub>3R</sub>, V<sub>4R</sub>, V<sub>5R</sub></i>	II
<b>6-wire, ECG2</b>	Set the unit default lead.	<i>I, II, III, MCL, AVR, AVL, AVF, V<sub>1</sub>, V<sub>2</sub>, V<sub>3</sub>, V<sub>4</sub>, V<sub>5</sub>, V<sub>6</sub>, V<sub>7</sub>, V<sub>8</sub>, V<sub>9</sub>, V<sub>3R</sub>, V<sub>4R</sub>, V<sub>5R</sub></i>	V <sub>2</sub> ; V lead choice is determined by Va and Vb settings
<b>6-wire, ECG3</b>	Set the unit default lead.	<i>I, II, III, MCL, AVR, AVL, AVF, V<sub>1</sub>, V<sub>2</sub>, V<sub>3</sub>, V<sub>4</sub>, V<sub>5</sub>, V<sub>6</sub>, V<sub>7</sub>, V<sub>8</sub>, V<sub>9</sub>, V<sub>3R</sub>, V<sub>4R</sub>, V<sub>5R</sub></i>	III
<b>6-wire, ECG4</b>	Set the unit default lead.	<i>I, II, III, MCL, AVR, AVL, AVF, V<sub>1</sub>, V<sub>2</sub>, V<sub>3</sub>, V<sub>4</sub>, V<sub>5</sub>, V<sub>6</sub>, V<sub>7</sub>, V<sub>8</sub>, V<sub>9</sub>, V<sub>3R</sub>, V<sub>4R</sub>, V<sub>5R</sub></i>	V <sub>5</sub> ; V lead choice is determined by Va and Vb settings

Unit Settings - NBP Setup			
Control	Function	Settings	Factory Default
<b>Patient Type</b>	Set patient type used for NBP alarm limits.	<i>Adult</i> <i>Pediatric</i>	Adult
<b>NBP Alarm</b>	Set NBP alarm notification.	<i>Systolic or Diastolic</i> <i>Systolic</i> <i>Diastolic</i> <i>Mean</i> <i>Off</i>	Systolic or Diastolic
<b>Systolic High</b>	Increment/decrement NBP high alarm limit by 5.	<i>Limit Maximum is 260</i> <i>Limit Minimum is 10</i>	160 Adult 120 Pediatric
<b>Systolic Low</b>	Increment/decrement NBP low alarm limit by 5.	<i>Limit Maximum is 260</i> <i>Limit Minimum is 10</i>	90 Adult 70 Pediatric
<b>Diastolic High</b>	Increment/decrement NBP high alarm limit by 5.	<i>Limit Maximum is 260</i> <i>Limit Minimum is 10</i>	90 Adult 70 Pediatric
<b>Diastolic Low</b>	Increment/decrement NBP low alarm limit by 5.	<i>Limit Maximum is 260</i> <i>Limit Minimum is 10</i>	50 Adult 40 Pediatric
<b>Mean High</b>	Increment/decrement NBP high alarm limit by 5.	<i>Limit Maximum is 260</i> <i>Limit Minimum is 10</i>	110 Adult 90 Pediatric
<b>Mean Low</b>	Increment/decrement NBP low alarm limit by 5.	<i>Limit Maximum is 260</i> <i>Limit Minimum is 10</i>	60 Adult 50 Pediatric

Unit Configurable Settings (IIC)

Unit Settings - Alarms			
Control	Function	Settings	Factory Default
<b>ECG Leads Off</b>	Adjust the severity level of this technical alarm (INOP).	<i>Cyan</i> <i>Yellow</i> <i>Red</i>	Cyan
<b>Replace Battery</b>	Adjust the severity level of this technical alarm (INOP).	<i>Cyan</i> <i>Yellow</i> <i>Red</i>	Cyan
<b>Yellow</b>	Set latched/non-latched status for SpO <sub>2</sub> , ST, and other non-arrhythmia yellow alarms.	<i>Latched</i> <i>Non-latched</i>	Latched
<b>Reminders</b>	Enables alarm reminders.	<i>Enable</i> <i>Disable</i>	<i>Enable</i>



## Global Settings (IIC iX)

The following tables identify the settings (and available choices) through the Alarm Management, Telemetry Setup, and ECG Management menus from the Global Settings application page at the IntelliVue Information Center iX. For more information, including information on Telemetry Profiles, see the *IntelliVue Informaiton Center iX Clinical Configuration Guide*, Part Number 453564292621.

### Alarm Management

Control	Function	Setting Choices	Factory Default
Alarms Off Priority	Sets the types of alarms that can be paused for a configured amount of time from the IIC iX..	Red and Yellow Yellow Only (red alarms must be paused at the device) Not Allowed	Yellow Only
Alarms Off	Sets the amount of time all alarms will be paused if selected.	1, 2, or 3 minutes.	2 min
Audible Latching	Sets which alarms must be silenced even if the condition no longer exists (applies to non-arrhythmia alarms only).	Red and Yellow Red Only	Red&Yellow
Alarm Reminder	Sets the appearance and behavior of how an alarm will remind if the alarm condition consists (applies to non-arrhythmia alarms only).	On Realarm Off	On
Inop Reminder	Sets the appearance and behavior of how an Inop will remind if the Inop condition consists	On Realarm Off	On
Reminder Time	Sets the time period for Reminders.	1, 2, or 3 minutes	3 min
No Data Inop	Sets the severity of the NO DATA FROM MONITOR inop.	Hard (always for MX40) Soft	Hard
ECG Leads Off	Sets the severity for the ECG LEADS OFF Inop	Cyan Yellow Red	Cyan
Replace Battery	Sets the severity for the REPLACE BATTERY Inop.	Cyan Yellow Red	Cyan
Some ECG AI Inop	Allows for notification whenever the On/Off settings for ECG/Arrhythmia alarms differ from the current Profile.	On Off	On

## Global Settings (IIC iX)

Control	Function	Setting Choices	Factory Default
HR Alarms	Sets heart rate limit alarm type.	Short Yellow Yellow	Short Yellow

**Telemetry Setup**

Control	Function	Setting Choices	Factory Default
Telemetry Button	Determines the action when the Telemetry Button is pressed.	Nurse Call - generates nurse call alarm that is marked as an event in Alarm Review. Record - generates an automatic recording. Call & Record - Creates both the nurse call alarm and automatically starts a recording. Off	Nurse Call
Standby Duration	Sets the standby duration time when Standby is selected at the IIC iX. Standby Duration is always Infinite when selected at the MX40.	10 minutes 20 minutes 30 minutes 1 hour 2 hours 3 hours 4 hours Infinite	Infinite
Battery Gauge	Selects whether a battery gauge is displayed on the IIC iX for devices operating on battery power.	On Off	On
Remote Pause	Enables all alarms to be paused at the device for the same configured amount of time that they are paused at the Information Center.	On Off	Off
RF Auto Shutoff	Selects whether the device will shut off after ECG LEADS OFF for longer than 10 minutes and the SpO <sub>2</sub> sensor cable is not connected for longer than 10 minutes.	On Off	On
SRR Use Model	Selects whether the device will assign to patient monitor or cableless measurement device.	Look for Sensor Look for Monitor	Look for Monitor
SRR Fast Transition	Reduce the delay time when fast switching between the MX40 and the patient monitor	On Off	On

Control	Function	Setting Choices	Factory Default
Lead Placement	Determines the default lead placement.	Standard EASI	Standard
Screen-On Time	Determines how long the MX40 display is active by default.	1 min 2 min 5 min 15 min 30 min	1 min
Default Screen	Sets the default display screen.	2 Waves P (portrait) 1 Wave P (portrait) 2 Waves L (landscape) Chest Diagram	2 Waves P
Wave 1-4	Selects the waveforms that will be sent and stored. Wave 1 and Wave 2 will always be Primary and Secondary Lead respectively.	ECG Pleth Resp	Wave 1 and Wave 2 will always be Primary and Secondary Lead respectively. ECG

### ECG Management

Control	Function	Settings	Factory Default
Primary Lead	Sets which lead will default to the Primary Lead for ECG analysis.	1, II, III, aVR, aVF, aVL, V1-6, V7-9, V3R - V5R	II
Secondary Lead	Sets which lead will default to the Secondary Lead for ECG Multi Analysis.	1, II, III, aVR, aVF, aVL, V1-6, V7-9, V3R - V5R	V2
Va Lead	Sets the default Va lead label.	V1-6, V7-9, V3R-V5R	V2
Vb Lead	Sets the default Vb lead label.	V1-6, V7-9, V3R-V5R	V5
Filter	Sets the filter on the ECG wave display.	0.5-40 Hz M 0.05-40 Hz ST	0.5-40 Hz M
Hexad (Va, Vb)	Sets the lead pairs for derived 12-lead ECG.	Off V1, V3 V1, V4 V1, V5 V2, V4 V2, V5 V3, V5 V3, V6	Off

Global Settings (IIC iX)

## 12. Operating with Information Center Release L or M

This section covers performance differences when operating the MX40 with previous releases of the Information Center (Release L or M).

Display .....	12-2
Alarms.....	12-3

Display

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## Display

An MX40 operating with either Release L or M of the Information Center has two screens showing either one measurement waveform and four numeric parameter values or the ECG lead placement chest diagram along with two numeric parameter values, depending on configuration.

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## Alarms

An MX40 operating with Release L or M of the Information Center does not have physiological alarm capability locally at the device (networked or non-networked). A **No Alarm Display** message is present along with the **Alarms Paused** icon.

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### Cautions

- When operating with Information Center Release L or M, the alarm pause time of the MX40 is not configurable. The alarm pause time for the MX40 is always two minutes.
  - When operating with Information Center Release L or M, if alarms are paused at the Information Center, the "Alarms Paused" message is only displayed at the Information Center.
- 

Technical alarms (INOPs) are communicated and can be silenced using the **Alarm Silence** button.

Technical alarms can be reviewed using the **Alarms** SmartKey.

**Note** — Not all rechargeable battery technical alarms are communicated via the Alert Data Integration paging system. The following alarms are not communicated:

- TELE CHECK BATT
- TELE SERVICE BATT
- TELE BATTERY TEMP

However, these technical alarms are still transmitted to the Information Center.

Alarms



## 13. Trends

This section covers the Trend functionality of the MX40. Trends are patient data collected over time and displayed in tabular form to give you a picture of how your patient's condition is developing. Trend information is stored in the MX40 for continuously-monitored measurements, such as ECG, as well as for aperiodically-measured parameters, such as SpO<sub>2</sub>. One hour of Trend information is standard on the MX40, with the option available for 24 hours.

Viewing Vital Trend Information ..... 13-2

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## Viewing Vital Trend Information

➤ ***To view Vital Trend information:***

- 1 Touch the SmartKeys button.
- 2 From the **SmartKeys** menu, select **Vitals Trend**.

➤ ***To change the time columns:***

- 1 Touch the time column.
- 2 Select a different time period.

# 14. Maintenance

This section provides procedures for maintaining the MX40 after installation, including equipment label assignment, cleaning and battery care.

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## Cleaning

The procedure in this section keeps the MX40 and its accompanying patient cable clean and provides protection against infectious agents and bloodborne pathogens. Both the outside and the inside of the MX40 battery compartment and the patient cable must be kept free of dirt, dust, and debris.

**Note** — Single-Patient-Use leadsets are intended to be disposed of when use is complete. They are not to be re-used and are not designed to be cleaned using any of the materials listed below.

**Important** — After exposure, the MX40 and the patient cable must be cleaned as per the instructions contained herein. Sterilization of the MX40 has been qualified using the STERRAD 100NX System. For more information and instruction on sterilizing the MX40, contact your service personnel. The alternative Steris V-pro process using hydrogen peroxide vapor is also acceptable.

➤ ***Perform the following steps to clean the MX40 and the patient cable of visible surface contamination.***

**Note** — when cleaning, the use of protective gloves is encouraged.

- 1 Remove the batteries and disconnect the patient cable.
- 2 If using disposable AA batteries, remove the battery tray and clean separately.
- 3 Wipe the MX40 and the patient cable clean by using a cloth dampened modestly with one of the approved cleaning agents listed in the table below.
- 4 Follow the manufacturer's instructions with regard to application duration.
- 5 Wipe the M40 and inside the patient cable housing with distilled water or alcohol to prevent residue build-up.
- 6 Allow to air-dry, or dry with a non-lint producing cloth.

## Cleaning Materials for the MX40

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### Caution

- Use of abrasive cleaning materials, or disinfectants or cleaning agents not listed herein, on any part or component of the MX40 may damage the components.

- The Gore-tex patch in the battery compartment of the MX40 can be damaged by the use of glutaraldehyde and anti-bacterial soap.
- Sharp or pointed instruments should not be used to remove soil from recessed areas on the MX40.

### Approved Cleaners

Cleaner	Active Ingredient
Isopropyl Alcohol based	Isopropyl Alcohol ( $\geq 70\%$ )
Hydrogen Peroxide	Hydrogen Peroxide (3%)
Chlorine Bleach	Sodium Hypochlorite (1:10 concentration, mixed < 24 hours)
Metrex CaviWipes	Isopropyl alcohol (15-18%) Sodium hydroxide (0.1%) 2-butoxyethanol (1-5%)
Viraguard	Isopropanol (70%)
Resert XL HLD	Hydrogen peroxide (1.4-2-3%) 2-Fumic Acid (<2.5%)
Sporox II Sterilizing & Disinfection Solution	Hydrogen peroxide (7.5%) Phosphoric acid (0.85%)
Sanicloth Plus Germicidal Cloths	Isopropyl alcohol (55%) Quaternary ammonium (0.5%)
WipesPlus Disinfecting Wipes	Phenylphenol (0.28%), Benzyl-p-chlorophenol (0.03%)
TechSpray General Purpose Cleaner	Isopropyl alcohol (70%)
Oxivir Tb Cleaner Disinfectant	Hydrogen peroxide (2.5-3.5%)
Oxivir Tb Wipes	Hydrogen peroxide (3%)
Sanicloth HB	Quaternary ammonium (1%)
Sanicloth Plus	Quaternary ammonium (0.25%) 2-Butoxyethol (1-4%) Isopropyl alcohol (14.85%)
Super Sanicloth	Quaternary ammonium (<1%) Isopropyl alcohol (55%)
Sanicloth Bleach Germicidal Disposable Wipes	Sodium Hypochlorite (0.6%)

## Cleaning

Cleaner	Active Ingredient
Bacillol 25	Ethanol (100 mg/g) Propane-2-ol (90 mg/g) Propane-1-ol (60 mg/g)
Bacillol AF	Propane-1-ol (450 mg/g) Propane-2-ol (250 mg/g) Ethanol (47 mg/g)
Hydrogen Peroxide	Hydrogen peroxide (5%)
Meliseptol	Propane-1-ol, (50 g) Glyoxal (0.08 g / 100 g)

**Note** —The cleaners listed above are also suitable for cleaning the patient cable and the lithium-ion battery.

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## Disposing of the MX40

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### Warning

To avoid contaminating or infecting personnel, the environment or other equipment, make sure you disinfect and decontaminate the MX40 appropriately before disposing of it in accordance with your country's laws for equipment containing electrical and electronic parts. For disposal of parts and accessories where not otherwise specified, follow local regulations regarding disposal of hospital waste.

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You will find detailed disposal information on the following web page:

<http://www.healthcare.philips.com/main/about/Sustainability/Recycling/pm.wpd>

The Recycling Passports located there contain information on the material content of the equipment, including potentially dangerous materials which must be removed before recycling (for example, batteries and parts containing mercury or magnesium).

Do not dispose of waste electrical and electronic equipment as unsorted municipal waste. Collect it separately, so that it can be safely and properly reused, treated, recycled, or recovered.

---

## Label Assignment for Replacement MX40

During installation, an equipment label is assigned to each MX40 in a clinical unit so that the device can be identified during operation within the wireless system. If an MX40 is lost, the Assign Label function at the Information Center enables you to unassign the label from a lost device, and re-assign its label to a replacement device. Labels are limited to those available in an individual clinical unit.

### Re-assigning an Equipment Label at the IntelliVue Information Center

➤ ***To re-assign an equipment label to a replacement device:***

- 1 At the Information Center, clear the sector that the original equipment label was assigned to (**Patient Window -> Sector Setup -> Clear Sector -> OK**).
- Note** — Before clearing the sector, ensure that the equipment label of the lost device is not actively assigned to a patient being monitored.
- 2 Select **All Controls -> Label Assignment**.
- 3 Enter password.
- Note** — The remaining screens will be in English only.
- 4 Insert battery power into the MX40 and if attached, disconnect the patient cable.
- 5 Select **Refresh**.
- 6 Select the MAC address of the replacement device from the **New Devices** list. If the address does not appear, remove battery power and re-insert. Select **Refresh**.
- Note** — The MAC address appears on the rear label of the MX40.
- 7 Select the equipment label that was assigned to the previous device from the **Equipment Label** list.
- 8 Select **Assign Label** to initiate programming of the equipment label into the replacement MX40.
- 9 When prompted, press **Confirm** on the MX40 to accept the assignment. The confirmation must occur within 30 seconds of the prompt.
- 10 Wait for the new\_device label to change to the selected equipment label.
- 11 In **Sector Setup**, select the **Bed Label** and **Equipment Label** and then press **OK**.



## Re-assigning an Equipment Label at the IntelliVue Information Center iX

➤ ***To re-assign an equipment label to a replacement device:***

- 1 Enter the **Manage Unit** application (scroll down if necessary).
- 2 Select **Label Assignment**.
- 3 Select the entry for both the previously assigned device (on the left) and the entry for the available device (on the right).
- 4 Select **Replace**.
- 5 At the MX40, select **Confirm**.
- 6 At the Information Center iX, select **OK**.
- 7 Select Refresh to confirm that the device now appears in the **Assigned Devices** column.
- 8 Confirm that the Equipment Label is now displayed on the MX40.

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## Charging Lithium-ion Rechargeable Batteries

The li-ion rechargeable battery is recharged using the IntelliVue CL Charging Station.

To charge a battery, place it onto a charger slot on the charging station. The battery power indicators will supply information about the charge status.

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### Warning

- Always use the supplied power cord with the grounded mains plug to connect the charging station to a grounded AC mains socket. Never adapt the mains plug from the power supply to fit an ungrounded AC mains socket.
  - Do not use AC mains extension cords or multiple socket outlets. If a multiple portable socket outlet without an approved isolation transformer is used, the interruption of its protective grounding may result in leakage currents equal to the sum of the individual ground leakage currents, so exceeding allowable limits.
  - Do not connect any devices that are not supported as part of the system.
- 

## Battery Power Indicators

There are various indications which help you keep track of the battery power status.

- LEDs on the charging station slots
- battery status information on both the MX40 and the charging station's display
- INOP messages

The indicators always show the remaining capacity in relation to the battery's actual maximum capacity which may lessen as the battery ages.

### Charging Station LEDs

The nine charger slot LEDs show the battery status of the device in their slot and are switched off if no battery is inserted.

If a battery is put on a charging station slot, the corresponding LED will flash yellow until the battery's current state has been identified. Then a beep is issued and the LED reflects the battery status as described in the table below.

Status	LED
no battery on charger slot	off
battery put on charger slot	flashing yellow
battery not properly recognized, error	cyan
battery recognized, battery charging	yellow
battery recognized, battery full ( $\geq 90\%$ )	green

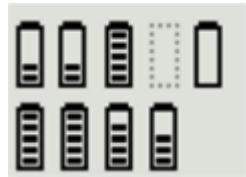
The **AC Power / Error LED** is

- green when the charging station is connected to AC power
- cyan during startup or to indicate a general charging station error

**Note** — Wiping of battery contacts with an alcohol solution after cleaning is recommended.

## Battery Status on the Charging Station Display

The IntelliVue CL Charging Station display provides a quick overview of all the connected devices and their battery status. The screen is arranged in the same layout as the charger slots.



## Battery Lifetime Management

The lifetime of a li-ion battery depends on the frequency and duration of use. When properly cared for, the useful life is approximately 4 years or 500 complete charge-discharge cycles, whichever comes first. In addition, experience indicates that the incidence of failure may increase with battery service life due to the accumulated stresses of daily use. We therefore strongly recommend that li-ion batteries be replaced after 2 years or 500 complete charge-discharge cycles.

The age of a li-ion battery begins at the date of manufacture. The date of manufacture is listed on the side of the battery.

## Charging Lithium-ion Rechargeable Batteries

### **Battery Disposal**

Discharge the battery and insulate the terminals with tape before disposal. Dispose of used batteries promptly and in accordance with local recycling regulations.

# 15. Safety Standards & Specifications

This section describes the regulatory standards that the IntelliVue MX40 complies with, along with product and measurement specifications.

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## Regulatory Information

### Software Hazard Prevention

Potential hazards arising from errors in the software program have been identified. Mitigations applied to reduce the associated risk of such hazards are included as part of the Risk Management, Clinical Evaluation, and Verification and Validation phases of the product's development.

### AC Power Source

The system is not intended for connection to the public mains as defined in CISPR-11.

### Industrie Canada Compliance (Canada)

This Class B ISM device complies with Canadian ICES-001.

Cet ISM de la classe B est conforme à la norme NMB-001 du Canada.

### Safety Standards

The device complies with the following safety requirements for medical electrical equipment:

- EN 60601-1:1990 + A1:1993 + A2:1995 + A11:1993 + A12:1993 + A13:1996 General Requirements for Safety (with worldwide deviations, including U.S. deviations)
- CSA C22.2 #601.1:1992 Medical Electrical Equipment - General Safety
- UL 60601-1 Medical Electrical Equipment - General Safety
- UL 2054 Standards for Household and Commercial Batteries
- EN 60601-1-1:2006 System Requirements
- EN 60601-1-4:2000 Safety Requirements for Programmable Electronic Medical Systems
- EN 50371:2005 Low Power Electronic and Electronic Apparatus Electromagnetic Exposure
- EN ISO 9919:2005 Requirements for SpO<sub>2</sub> Pulse Oximeters
- EN ISO 10993-1:2003 Biocompatibility
- EN ISO 10993-1:2003 Biocompatibility (for leadwires and pouch)
- EN ISO 9919:2005 Pulse Oximeters

- IEC 60601-1-2:2001 Electromagnetic Compliance
- IEC 60601-1-4:1999 +A1 Requirements for Programmable Electrical Medical Systems
- IEC 60601-1-6:2006 General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-8:2006 General Requirements for Safety for Alarm Systems
- IEC 60601-2-49:2001 Particular Requirements for Safety for Patient Monitoring Equipment
- IEC 60601-2-27:2005 Particular Requirements for Safety for Electrocardiograph Monitoring Equipment
- IEC 62133:2002 Safety Requirements for Portable Sealed Secondary Cells (alkaline, lithium-ion)
- AAMI EC 13:2007 Performance Standard, Cardiac Monitors
- AAMI EC 53:1995 (R) 2001 ECG Cables/Leadwires (excluding 4.2.1)

## **Intended Use Statement**

Intended for monitoring and recording of and to generate alarms for, multiple physiological parameters of adults and pediatrics in a hospital environment and during patient transport inside hospitals. Not intended for home use. Intended for use by health care professionals.

## **Indications for Use**

Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. Intended for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults and pediatrics in hospital environments and during transport inside hospitals.

## **Intended Uses of MX40**

The MX40 is to be used primarily as a traditional telemetry medical device. It connects to the IntelliVue Information Center by way of a wireless network. When the MX40 is connected the IntelliVue Information Center the IntelliVue Information Center provides the primary patient monitoring and alarming function. The MX40 does not automatically provide local monitoring or alarming when connected to the Information Center.

## Regulatory Information

The MX40 can provide time-limited local monitoring when it is not connected to the wireless network.

Unlike a traditional bedside monitor which operates on AC power, the MX40 is powered by battery and cannot provide continuous monitoring.

## Authorized EU Representative

Philips Medizin Systeme Deutschland  
Hewlett-Packard-Strasse 2  
D 71034, Boeblingen  
Germany

## Patient Population

This device is not for use with infant or neonatal patients.

Clinical judgment must be used to determine when the MX40 should be used on a specific pediatric patient, as it is not possible to assign a precise weight or age to ECG performance.

Use of the device is restricted to one patient at a time.

The components/accessories which come into contact with the patient's skin are in compliance with the relevant requirements of EN ISO 10993-1 for Biocompatibility. The device is not designed for direct contact with the patient's skin. The accompanying pouch is the appropriate means for holding the device.

## Rx

Federal Law restricts this device to sale by or on the order of a physician.

## Essential Performance

The IntelliVue MX40 provides Essential Performance (EP) under normal operating conditions (includes EMC exposure) only as a complete Medical Electrical System, consisting of the MX40, MPx companion monitor (Optional), IntelliVue CL SpO<sub>2</sub> and NBP Cableless Measurement devices(Optional), IntelliVue Telemetry Network Infrastructure, and the Information Center.



The System achieves its Essential Performance exclusively through alarm generation at the IntelliVue Information Center and locally at the MX40, based on configuration.

The IntelliVue MX40 protects the patient from unacceptable immediate clinical risk by generating specific Physiological Alarms when appropriate. If the system cannot generate Physiological Alarms, then relevant Severe or Hard-Level Technical Alarms (Inops) are created.

## Risk Management Considerations

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### Warning

The MX40 operates exclusively via a wireless network connection, therefore, it should not be used for primary monitoring in applications where momentary loss of the ECG is unacceptable at the Information Center. It sends ECG and optionally pulse oximetry data to the Information Center, where the Information Center displays real-time patient data, provides alarm annunciation, data storage and review applications. The ECG waveform data, alarms and optionally SpO<sub>2</sub> can always be viewed on the MX40 regardless of the connection to the Information Center.

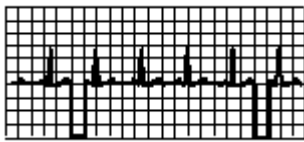
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Smart Hopping technology alleviates most of the problems associated with legacy telemetry technologies. Reception problems are less frequent, because Smart Hopping avoids interference and moves to a different access point if the signal strength is too low. The level of radio frequency activity is always fluctuating in the environment. If the level becomes high enough to significantly interfere with transceiver operation, the system responds by moving to another "cleaner" area where there is less activity.

### Dropouts

Because the MX40 operates exclusively via a wireless network connection, under certain frequency conditions dropouts can occur. Dropouts result from a weak signal or RF interference, and appear on the waveform when the signal "drops" to the bottom of the channel for a minimum of 200 ms. If dropouts are frequent enough to affect the heart rate count, the "Cannot Analyze ECG" or "Cannot Analyze ST" technical alarm occurs. If there are enough dropouts to cause disassociation/reassociation with the Information Center, events in the Clinical Review application can reflect loss of data for up to 1 minute in the worst case.

## Regulatory Information

Problem	Cause	Remedy
Dropouts 	Low signal strength RF interference	See "Signal Strength" below. See "Radio Frequency Interference" below.

**Monitoring Considerations**

- Patient should be restricted to the designated coverage area. Monitoring performance will degrade if patients go outside the radius of coverage of the receiving wireless network.
- A patient location strategy is critical to a telemetry system. If a life-threatening event occurs, the clinician must be able to locate the patient quickly. The importance of this increases as the coverage area increases.
- Frequency management is the responsibility of the hospital. Philips Healthcare has no control over the RF environment in the hospital. If interference exists at the operating frequencies of the telemetry equipment, telemetry performance will be affected. Careful selection of frequencies for all wireless devices used within a facility (transceivers, other wireless medical devices, etc.) is important to prevent interference between them.

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**Caution****IEC/ANSI/AAMI 80001-1:2010**

Philips recognizes the importance of a safe and effective network that meets both the business needs of a healthcare facility, IT networking requirements, and the clinical functionality. Philips supports the IEC 80001-1 standard in regards to working as a partner with a healthcare organization in the design, implementation, and management of the Medical IT-Network to properly provision and support not only Philips devices, but all the devices using the network. Applying the principles of risk management to hospital frameworks is highly encouraged.

When operating the MX40 on a Customer Supplied Clinical Network, Philips strongly encourages our customers to perform risk management of their Medical IT-Network infrastructure in accordance with IEC 80001.

If the MX40 experiences loss of network connectivity, technical alerts at the Information Center ("No Signal") and at the MX40 ("No Central Monitor") will occur. The MX40 will also automatically revert to local monitor mode which activates display of patient data on the MX40 – however, when in this state, battery life will be shortened.

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## Electromagnetic Compatibility

Medical electrical equipment can either generate or receive electromagnetic interference. This product has been evaluated for electromagnetic compatibility (EMC) with the appropriate accessories according to IEC 60601-1-2:2001, the international standard for EMC for medical electrical equipment. This IEC standard has been adopted in the European Union as the European Norm, EN 60601-1-2:2001.

Radio frequency (RF) interference from nearby transmitting devices can degrade performance of the product. Electromagnetic compatibility with surrounding devices should be assessed prior to using the product.

Fixed, portable, and mobile radio frequency communications equipment can also affect the performance of medical equipment. See your service provider for assistance with the minimum recommended separation distance between RF communications equipment and the product.

The cables, sensors/transducers, and other accessories for which compliance is claimed are listed in the Service and User documentation accompanying the product.

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### Warnings

- The use of accessories, transducers and cables other than those specified in the product service and user documentation can result in increased electromagnetic emissions or decreased immunity of the product.
  - Short-range radio connections are subject to interruption due to interference from other radio sources in the vicinity, including microwaves, bluetooth devices, and DECT phones. Outside the frequency band and 5% above and below, i.e. the exclusion band according to IEC 60601-1-2, the short-range radio connection is immune up to 3V/m in the frequency range from 80MHz to 2.5 GHz. Depending on the strength and duration of the interference, the interruption may occur for an extended period. Any interruption of the signal due to interference, moving out of range, or for other reasons is indicated with a Tele Disconnected INOP message.
  - The product should not be used next to or stacked with other equipment. If you must stack the product, you must check that normal operation is possible in the necessary configuration before the product is used on patients.
-

## Reducing Electromagnetic Interference

The MX40 and associated accessories can be susceptible to interference from other RF energy sources and continuous, repetitive, power line bursts. Examples of other sources of RF interference are other medical electrical devices, cellular products, information technology equipment, and radio/television transmission. If interference is encountered, as demonstrated by artifact on the ECG or dramatic variations in physiological parameter measurement values, attempt to locate the source. Assess the following:

- Is the interference due to misplaced or poorly applied electrodes or sensors? If so, re-apply electrodes and sensors correctly according to directions in Chapter 6.
- Is the interference intermittent or constant?
- Does the interference occur only in certain locations?
- Does the interference occur only when in close proximity to certain medical electrical equipment?

Once the source is located, attempt to attenuate the interference by distancing the MX40 from the source as much as possible. If assistance is needed, contact your local service representative.

## Restrictions for Use

Artifact on ECG and other physiological waveforms caused by electromagnetic interference should be evaluated by a physician or physician authorized personnel to determine if it will negatively impact patient diagnosis or treatment.

## Electromagnetic Compatibility (EMC) Specifications

Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment. You must operate your monitoring equipment according to the EMC information provided in this book. Portable and mobile radiofrequency (RF) communications equipment can affect medical electrical equipment.

### Accessories Compliant with EMC Standards

All accessories listed in the accessories section comply, in combination with the MX40, with the requirements of IEC 60601-1-2:2001 + A1:2004.

## Electromagnetic Compatibility

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**Warning**

Using accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the monitoring equipment.

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**Electromagnetic Emissions**

<b>Emissions Test</b>	<b>Compliance</b>	<b>Avoiding Electromagnetic Interference</b>
Radio Frequency (RF) emissions	Group 1	TheMX40 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The MX40 is suitable for use in all establishments.
Harmonized emissions	Not Applicable	Device is battery powered only
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Not Applicable	

**Electromagnetic Immunity**

The MX40 is suitable for use in the specified electromagnetic environment. The user must ensure that it is used in the appropriate environment as described below.

<b>Immunity Test</b>	<b>IEC 60601-1-2 Test Level</b>	<b>Compliance Level</b>	<b>Electromagnetic Environment Guidance</b>
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment

## Recommended Separation Distance

### Warning

The MX40, equipped with a wireless network interface, intentionally receives RF electromagnetic energy for the purpose of its operation. Therefore, other equipment may cause interference, even if that other equipment complies with CISPR emission requirements.

In the following table, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Portable and mobile RF communications equipment should be used no closer to any part of the MX40, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with this

symbol: 

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 VRMS	Recommended separation distance: $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Recommended separation distance: 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ 800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$

## Electromagnetic Compatibility

Field strengths from fixed transmitters, such as base stations for radio (cellular, cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the monitor is used exceeds the applicable RF compliance level above, the MX40 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the monitor.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

The MX40 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the monitor as recommended below, according to the maximum output power of the communications equipment.

In the following table, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Frequency of Transmitter	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
Equation	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
Rated max. output power of transmitter	Separation distance	Separation distance	Separation distance
0.01 W	0.1 m	0.1 m	0.2 m
0.1 W	0.4 m	0.4 m	0.7 m
1 W	1.2 m	1.3 m	2.3 m
10 W	3.8 m	3.8 m	7.3 m
100 W	12.0 m	12.0 m	23.0 m



## **Electrosurgery Interference/Defibrillation/Electrostatic Discharge**

The equipment returns to the previous operating mode within 10 seconds without loss of any stored data. Measurement accuracy may be temporarily decreased while performing defibrillation. This does not affect patient or equipment safety. Do not expose the equipment to x-ray or strong magnetic fields (MRI). The MX40 is not for use during electrosurgery.

## **Restart Time**

After power interruption, an ECG wave will be shown on the display after 30 seconds maximum.

## Battery Specifications

## Battery Specifications

### Battery Life

The battery life specifications listed below are based on the use of three Duracell MN 1500 batteries. Battery life for other brands may differ.

<b>Telemetry Mode Networked (Display Off)</b>	<b>Battery Life (1.4GHz p/n 865350)</b>	<b>Battery Life (2.4GHz p/n 865351)</b>
ECG Only (only one radio active)	24.9 hours	24.7 hours
ECG/SpO <sub>2</sub> Continuous (using legacy SpO <sub>2</sub> cable/sensors. Only one radio active.)	11.2 hours	8.9 hours
ECG/SpO <sub>2</sub> Manual	In this mode battery life is dependent on the usage rate and will range between the ECG Only battery life and the ECG/SpO <sub>2</sub> Continuous battery life.	

<b>Monitor Mode Networked (Display On)</b>	<b>Battery Life (1.4GHz p/n 865350)</b>	<b>Battery Life (2.4GHz p/n 865351)</b>
ECG Only (only one radio active)	11 hours	7.7 hours
ECG/SpO <sub>2</sub> Continuous (using legacy SpO <sub>2</sub> cable/sensors. Only one radio active.)	5.3 hours	2.9 hours
ECG/SpO <sub>2</sub> Manual	In this mode battery life is dependent on the usage rate and will range between the ECG Only battery life and the ECG/SpO <sub>2</sub> Continuous battery life.	

<b>Monitor Mode Non-networked (Display On)</b>	<b>Battery Life (1.4GHz p/n 865350)</b>	<b>Battery Life (2.4GHz p/n 865351)</b>
ECG Only (only one radio active)	6.8 hours	7.3 hours
ECG/SpO <sub>2</sub> Continuous (using legacy SpO <sub>2</sub> cable/sensors. Only one radio active.)	4.7 hours	4.6 hours

## Battery Specifications

<b>Monitor Mode Non-networked (Display On)</b>	<b>Battery Life (1.4GHz p/n 865350)</b>	<b>Battery Life (2.4GHz p/n 865351)</b>
ECG/SpO <sub>2</sub> Manual	In this mode battery life is dependent on the usage rate and will range between the ECG Only battery life and the ECG/SpO <sub>2</sub> Continuous battery life.	

The battery life specifications listed below are based on the use of the Philips Rechargeable Lithium-ion battery.

<b>Telemetry Mode Networked (Display Off)</b>	<b>Battery Life (1.4GHz p/n 865350)</b>	<b>Battery Life (2.4GHz p/n 865351)</b>	<b>Battery Life (WLAN p/n 865352)</b>
ECG Only (only one radio active)	26.1 hours	25.1	25 hours
ECG/SpO <sub>2</sub> Continuous (using legacy SpO <sub>2</sub> cable/sensors. Only one radio active.)	15.6 hours	14.1	15 hours
ECG/SpO <sub>2</sub> Manual	In this mode battery life is dependent on the usage rate and will range between the ECG Only battery life and the ECG/SpO <sub>2</sub> Continuous battery life.		

<b>Monitor Mode Networked (Display On)</b>	<b>Battery Life (1.4GHz p/n 865350)</b>	<b>Battery Life (2.4GHz p/n 865351)</b>	<b>Battery Life (WLAN p/n 865352)</b>
ECG Only (only one radio active)	11 hours	10.4 hours	11 hours
ECG/SpO <sub>2</sub> Continuous (using legacy SpO <sub>2</sub> cable/sensors. Only one radio active.)	8 hours	7.8 hours	8 hours
ECG/SpO <sub>2</sub> Manual	In this mode battery life is dependent on the usage rate and will range between the ECG Only battery life and the ECG/SpO <sub>2</sub> Continuous battery life.		

<b>Monitor Mode Non-networked (Display On)</b>	<b>Battery Life (1.4GHz p/n 865350)</b>	<b>Battery Life (2.4GHz p/n 865351)</b>	<b>Battery Life (WLAN p/n 865352)</b>
ECG Only (only one radio active)	13 hours	10.4 hours	12 hours
ECG/SpO <sub>2</sub> Continuous (using legacy SpO <sub>2</sub> cable/sensors. Only one radio active.)	8.8 hours	7.8 hours	8.5 hours

## Battery Specifications

Monitor Mode Non-networked (Display On)	Battery Life (1.4GHz p/n 865350)	Battery Life (2.4GHz p/n 865351)	Battery Life (WLAN p/n 865352)
ECG/SpO <sub>2</sub> Manual	In this mode battery life is dependent on the usage rate and will range between the ECG Only battery life and the ECG/SpO <sub>2</sub> Continuous battery life.		

**Note** — Use of the short-range radio can reduce battery life by 25%.

**Note** — The battery capacity of re-chargeable batteries degrades over time and number of recharge cycles. Toward the end of its useful life, the battery capacity may be reduced by 25-30%. If this reduced battery life is unacceptable based on your use model, Philips recommends replacing the rechargeable battery sooner.

**Nominal Current**

Operating Mode	Nominal Current (p/n 865350)	Nominal Current (p/n 865351)	Nominal Current (p/n 865352)
ECG Only (Display inactive)	67 mA @ 3.6V	67 mA @ 3.6V	70 mA @ 3.6V
ECG/SpO <sub>2</sub> Continuous (Display inactive)	136 mA @ 3.6V	136 mA @ 3.6V	140 mA @ 3.6V

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## Lithium-ion Battery Charge Time

Definition	Charging Method	Charge Time
Battery pack charge time from 90% depletion state	The Lithium-ion Battery Pack is charged on a separate external charging station. It must be removed from the MX40 to charge.	6.5 hours

## Physical Specifications

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## Physical Specifications

Parameter	Specification
Height	126.8 mm (4.99 in)
Width	69.9 mm (2.75 in)
Depth	31.5 mm (1.24 in)
Weight <ul style="list-style-type: none"> <li>Without batteries, includes SpO<sub>2</sub> and short-range radio</li> <li>With 3 AA batteries, includes SpO<sub>2</sub> and short-range radio</li> <li>With lithium-ion battery, includes SpO<sub>2</sub> and short -range radio</li> </ul>	1.4 GHz - 240 g (8.5 oz) 2.4 GHz - 215 g (7.6 oz) WLAN - 206 g (7.3 oz)  1.4 GHz - 324 g (11.4 oz) 2.4 GHz - 298 g (10.5 oz) WLAN - 292 g (10.3 oz)  1.4 GHz - 314 g (11.1 oz) 2.4 GHz - 289 g (10.2 oz) WLAN - 274 g (9.7 oz)
Display <ul style="list-style-type: none"> <li>Type</li> <li>View Area</li> <li>Resolution</li> <li>Backlight</li> <li>ECG Display Sector Size (height)</li> <li>ECG Display Sweep Speed</li> <li>Resp Display Sweep Speed</li> </ul>	<ul style="list-style-type: none"> <li>2.8" QVGA Color LCD</li> <li>43.2mm x 57.6 mm (1.70" x 2.26")</li> <li>240 x 320</li> <li>White LED</li> <li>13.5mm (portrait), 9.9mm (landscape)</li> <li>10mm/s with 4.32 sec of viewable ecg data (portrait), 10mm/s with 5.76 sec of viewable ecg data (landscape)</li> <li>2.5mm/s with 17.28 sec of viewable resp data (portrait) 2.5mm/s with 23.04 sec of viewable resp data (landscape).</li> </ul>
Alarm Signal Sound Pressure Level	40dB(A) - 70dB(A)

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## MX40 1.4 GHz Smart-Hopping Radio

Parameter	Specification
Frequency Ranges	Bands: 1395-1400 MHz and 1427-1432 MHz Channel Spacing: 1.6 MHz
RF Output Power (existing systems)	8 dBm +2/-1.5 dB (4.5 mW to 10 mW), into antenna load
Radio Frequency Accuracy during normal operation	<+60/-100 KHz relative to channel frequency, includes temperature compensation and aging effects
Modulation Type	GFSK (1M40Q7D)
Out of Band Spurious Emission Levels: <= 1394 MHz, >= 1401 MHz <= 1428 MHz, >= 1433 MHz	<-41 dBm in 1 MHz bandwidth for FCC limit
Occupied bandwidth as defined by power in 99% BW	< +/- 800 KHz

### 1.4GHz WMTS (US only)

This device complies with Part 15 of the FCC Rules. Operation is subject to the condition that this device does not cause harmful interference. Operation of this equipment requires the prior coordination with a frequency coordinator designated by the FCC for the Wireless Medical Telemetry Service.

## MX40 2.4 GHz Smart-Hopping Radio

**MX40 2.4 GHz Smart-Hopping Radio**

Parameter	Specification
Frequency Range	ISM Band: 2400 - 2483.5 MHz
Channel Assignment	48 radio channels assigned from 2401.056 MHz - 2482.272 MHz Channel Spacing: 1.728 MHz
RF Output Power	FCC: Channels 0-46 -17 dBm +/- 1 dB (40 mW to 63 mW, nominal 50 mW), into antenna load. Channel 47 only - 15 dBm +/- 1 dB.  ETSI: 12 dBm +/- 1 dB (13 mW to 20 mW, nominal 16 mW), into antenna load  ARIB: 13.5 dBm +/- 1 dB (18 mW to 28 mW, nominal 22 mW), into antenna load
Radio Frequency Accuracy during normal operation	<+ 60 /- 100 KHz relative to channel frequency, includes temperature compensation and aging effects
Modulation Type	GFSK, Gaussian Frequency Shift keying (1M40Q7D)
Modulation Bandwidth	Typically 1.4 MHz (20 dB Bandwidth) Typically 980 KHz (6 dB Bandwidth)
Out of Band Spurious Emission Levels	Meets ETSI, RS210, FCC, ARIB standards

**2.4 GHz ISM**

FCC and Industry Canada Radio Compliance: This device complies with Part 15 of the FCC Rules and RSS-210 of Industry Canada. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Any changes or modifications to this equipment not expressly approved by Philips Medical Systems may cause harmful radio frequency interference and void your authority to operate this equipment.



The radio device used in this product is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC (Radio Equipment and Telecommunications Terminal Equipment Directive). Class 2 radio equipment. Member states may apply restrictions on putting this device into service or placing it on the market. This product is intended to be connected to the Publicly Available Interfaces (PAI) and used throughout the EEA.

This ISM device complies with Canadian ICES-001. Cet appareil ISM est conforme a la norme NMB-001 du Canada.

MX40 Short-Range Radio

## MX40 Short-Range Radio

Parameter	Specification
Frequency Ranges	ISM Band: 2400-2483.5MHz
Radio Channel assignment	16 Radio Channel assigned, $F_c = 2405 + 5 \cdot (k-11)$ MHz, $k=11,12,\dots,26$
Frequency Control	Configured via the bedside monitor or the Information Center depending on use model.
RF Output Power	-1.5 to -4.5 dBm $\pm 2/-3$ dB (0.7 mW to 0.3 mW), into Antenna load.
MX40 Frequency Accuracy during normal operation	$< \pm 40$ ppm, includes temperature compensation & aging effects
Modulation Type	Direct Sequence Spread Spectrum (DSSS), O-QPSK with half sine pulse shaping modulation (1M40Q7D)
Modulation Bandwidth	$> 500$ KHz, typically $\pm 950$ KHz (6dB Bandwidth), typically $\pm 1.4$ MHz (20dB Bandwidth)

## MX40 2.4GHz WLAN Radio

The MX40 2.4GHz/5.6GHz WLAN Radio conforms to the 802.11 a/b/g standard operating in the 2.4GHz and 5.6GHz ISM bands.

**Note** — For the MX40 WLAN device, Part Number 865352, use of the MX40's short-range Radio is only supported when operating with 802.11a (5.6GHz band).

The Radio characteristics are defined below.

WLAN Radio RF Specs	Specification
<b>802.11b</b>	
Technology	IEEE 802.11 b
Frequency Range	2.4 to 2.4835GHz
Transmitter Power	14 to 17 dBm into antenna load (RMS power)
Modulation	CCK (Complementary Code Keying)
Occupied Bandwidth, 99%	<22 MHz
<b>802.11g</b>	
Technology	IEEE 802.11 g
Frequency Range	2.4 to 2.4835GHz
Transmitter Power	12 to 15 dBm into antenna load (RMS power)
Occupied Bandwidth, 99%	<22 MHz
Modulation Type	OFDM (Orthogonal Frequency Division Multiplex)
Frequency Bands (802.11 b/g)	FCC, RS210, ETSI Japan{ARIB}, China, AU/NZ: 2.400 – 2.4835GHz
Out of Band Emissions (802.11 b/g)	Meets ETSI, RS210, FCC, ARIB, AU/NZ standards
<b>802.11a</b>	
Technology	IEEE 802.11 a
Frequency Power	5.15 to 5.825GHz
Transmitter Power	12 to 14 dBm into Antenna load (RMS power)
Occupied Bandwidth	≤ 18 MHz
Modulation	DSSS : OFDM (Orthogonal Frequency Division Multiplex)

## MX40 2.4GHz WLAN Radio

WLAN Radio RF Specs	Specification
Frequency Bands (802.11a)	FCC, RS210: 5.15 ~ 5.25Ghz, 5.25 ~ 5.35Ghz, 5.42 ~ 5.725Ghz, 5.725 ~ 5.825Ghz (excluding 5.6 ~5.65GH ETSI, AU/NZ: 5.15~ 5.35Ghz, 5.47 ~ 5.725Ghz Japan, ARIB: 5.150 – 5.250GHz, 5.25 – 5.35GHz, 5.470 – 5.725GHz, China: 5.725 ~5.825Ghz
Out of Band Emissions (802.11a)	Meets ETSI, RS210, FCC, ARIB, AU/NZ standards

## FCC and Industry Canada Radio Compliance

This device complies with Part 15 of the FCC Rules and RSS-210 of Industry Canada. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Any changes or modifications to this equipment not expressly approved by Philips Medical Systems may cause harmful radio frequency interference and void your authority to operate this equipment.

- The maximum antenna gain permitted (for devices in the 5250-5350 MHz and 5470-5725 MHz bands) complies with the e.i.r.p. limits as stated in RSS-210.
- The maximum antenna gain permitted (for devices in the 5725-5825 MHz bands) complies with the e.i.r.p. limits specified for point-to-point operation as stated in RSS-210.
- The device for band 5150-5250 MHz is only for indoor usage to reduce potential for harmful interference to co-channel mobile satellite systems.

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### Caution

High power radars are allocated as primary users of 5250-5350 MHz and 5650-5850 MHz. These radars could cause interference and/or damage to LE-LAN devices.

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## Environmental Specifications

Parameter	Specification
Temperature	
Operating	0 to 37° C (32 to 99° F)
Storage	-30° C to 50° C (-22° F to 122° F) without batteries 12° C to 35° C (53.6° F to 95° F) with Single-Patient-Use leadsets
Humidity	
Operating	< 95% RH at 37° C (98.6° F) non-condensing
Storage	< 90% RH at 50° C (122° F) without batteries
Altitude	
Operating & Non-operating	3,000 m (9,842 ft)
Barometric Pressure	72kPa (537 mmHg)

## Measurement Specifications

# Measurement Specifications

## ECG

Parameter	Specification
ECG channel transmitted Leads	
3 electrodes	Channel #1 = I, II, or III
5 electrodes	Channel #1 = II Channel #2 = III Channel #3 = MCL
5 electrodes, EASI	Channel #1 = Va-i Channel #2 = Va-s Channel #3 = Ve-s
6 electrodes	Channel #1= II Channel #2 = III Channel #3 = MCLa Channel #4 = MCLb
Resolution	5 $\mu$ V
ECG Input	Differential, defibrillator protected against 360 joules discharge into a 100 ohm load
Input Impedance	> 5 megohms (@ 10 Hz
Input Dynamic Range	+/- 9 mV
DC Offset Range	+/- 320 mV
CMRR	$\geq$ 90 dB @ 50, 60 Hz
Bandwidth +/- 3 dB	0.05 to 40 Hz
Gain Accuracy	+/- 5% at 25 °C (77 °F)
Noise Referred to ECG Input (Peak-to-Peak)	AAMI: 30 $\mu$ V (as per AAMI EC 13)
Lead Wires	3, 5 or 6-wire patient cable compatible with IntelliVue Patient Monitor, AAMI/IEC color codes
Time to baseline recovery from Defibrillator	AAMI: 5 s max (until ECG wave is on display but not yet centered, monitoring bandwidth)

## Measurement Specifications

Parameter	Specification																
Pacer Rejection Performance (Pace pulses with no tails).	<p>Positive pacers<sup>1</sup></p> <table> <tr> <td>Amplitude</td><td>Width</td></tr> <tr> <td>+2 to +700 mV</td><td>0.1, 0.2, 0.5 and 1.0 ms</td></tr> <tr> <td>+2 to +500 mV</td><td>1.5 ms</td></tr> <tr> <td>+2 to +400 mV</td><td>2 ms</td></tr> </table> <p>Negative pacers<sup>1</sup></p> <table> <tr> <td>Amplitude</td><td>Width</td></tr> <tr> <td>-2 to -700 mV</td><td>0.1, 0.2, 0.5 and 1.0 ms</td></tr> <tr> <td>-2 to -500 mV</td><td>1.5 ms</td></tr> <tr> <td>-2 to -400 mV</td><td>2 ms</td></tr> </table> <p><sup>1</sup> Philips does not claim, verify, or validate support for all available pacemakers.</p>	Amplitude	Width	+2 to +700 mV	0.1, 0.2, 0.5 and 1.0 ms	+2 to +500 mV	1.5 ms	+2 to +400 mV	2 ms	Amplitude	Width	-2 to -700 mV	0.1, 0.2, 0.5 and 1.0 ms	-2 to -500 mV	1.5 ms	-2 to -400 mV	2 ms
Amplitude	Width																
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-2 to -700 mV	0.1, 0.2, 0.5 and 1.0 ms																
-2 to -500 mV	1.5 ms																
-2 to -400 mV	2 ms																
EMC Performance Limits, radiated immunity	Meets Essential Performance.																
ECG Patient Cable Disconnection Safety	All ECG connections are patient safe within 750 msec of patient cable removal, with patient leakage current <10 $\mu$ A. Exception: Leadset detection pins are protected mechanically to prevent patient contact.																

## ECG Performance Disclosure/Specifications

Characteristic	Performance Disclosure/Specification (in italics)
Heart Rate Averaging Method	<p>Two different methods are used:</p> <ul style="list-style-type: none"> <li>Normally, heart rate is computed by averaging the 12 most recent RR intervals.</li> <li>If each of 3 consecutive RR intervals are greater than 1200 milliseconds (i.e. rate less than 50 b/min) for adult and pediatric patients, then the 4 most recent RR intervals are averaged to compute the HR.</li> </ul>
Heart Rate Meter Accuracy and Response to Irregular Rhythm	Provides correct heart rates (80, 60, 120, 90 b/min) using test waveforms as indicated in ANSI/AAMI EC13 Sec. 4. 1. 2. 1 (e).
Response Time of Heart Rate Meter to Change in Heart Rate	For a rate increase, the average time to reach the specified heart rate using test waveforms as indicated in ANSI/AAMI EC13 Sec. 4. 1. 2. 1 (f) is 10 seconds. For a rate drop, the average time is 7 seconds.

Measurement Specifications

Characteristic	Performance Disclosure/Specification (in italics)
Time to Alarm for Tachycardia	The ranges of time to alarm using test waveforms as indicated in ANSI/AAMI EC13 Sec. 4.1.2.1 (g) are 4 to 5 seconds.
Pacemaker Pulse Rejection Capability	Rejects pace pulses using test waveforms as indicated in ANSI/AAMI EC13 Sec. 4.1.4.1 (with amplitude from +/- 2 to +/- 700 mV, width from 0.1 to 2.0 ms).
Range and Accuracy of Heart Rate Meter	Meets the ANSI/AAMI EC13 Section 4.2.7 recommended minimum range and accuracy.  Heart rate range is 15 - 300 b/min for adults patients and 15-350 b/min for pediatric patients with accuracy of $\pm 1\%$ of the range. (Note: for rates equal to or less than 15, the displayed heart rate is 0).
Alarm Limit Range	Meets the ANSI/AAMI EC13 Section 4.2.8.1 standard. Lower alarm limit is 15 -295. Upper alarm limit is 20 - 300.
Resolution of Alarm Limit Settings	Meets the ANSI/AAMI EC13 Section 4.2.8.2 standard. The resolution is $\pm 5$ b/min.
Alarm Limit Accuracy	Meets the ANSI/AAMI EC13 Section 4.2.8.3 standard. Error less than $\pm 10\%$ or $\pm 5$ b/min
Time to Alarm for Cardiac Standstill	Meets the ANSI/AAMI EC13 Section 4.2.8.4 standard: maximum alarm time <10 seconds, using the test waveforms as indicated.
Time to Alarm for Low Heart Rate	Meets the ANSI/AAMI EC13 Section 4.2.8.5 standard: maximum alarm time <10 seconds, using the test waveforms as indicated.
Time to Alarm for High Heart Rate	Meets the ANSI/AAMI EC13 Section 4.2.8.6 standard: maximum alarm time <10 seconds, using the test waveforms as indicated.
Alarm Silencing	The time required for reactivation of a latched, silenced alarm is 3 minutes
ECG Waveform Display Time Base Accuracy	<i>Meets the ANSI/AAMI EC13 Section 4.2.9.6 standard: maximum error = +/-10%.</i>
Channel Width	<i>Meets the ANSI/AAMI EC13 Section 4.2.9.7(a) standard: minimum = 30mm.</i>
Trace Width	<i>Meets the ANSI/AAMI EC13 Section 4.2.9.7(b) standard: maximum = 1.0mm.</i>
Aspect Ratio	<i>Meets the ANSI/AAMI EC13 Section 4.2.9.7(f) standard: <math>0.4 \pm 0.08</math> s/mV.</i>
Input Signal Reproduction Accuracy: Overall Error	<i>Meets the ANSI/AAMI EC13 Section 4.2.9.8(a) standard: maximum = +/- 20%.</i>
Frequency Response: Sinusoidal	<i>Meets the ANSI/AAMI EC13 Section 4.2.9.8(b) standard: 0.67 to 40 Hz (3 db down).</i>



Characteristic	Performance Disclosure/Specification (in italics)
Frequency Response: Triangular	<i>Meets the ANSI/AAMI EC13 Section 4.2.9.8(b) standard: 0 to 25% reduction.</i>
Impulse Response: (for waves marked with ST bandwidth)	<i>Meets the ANSI/AAMI EC13 Section 4.2.9.8(c) standard: displacement maximum = 0.1 mV; slope maximum = 0.30 mV/s.</i>
Pacemaker Pulse Display Capability	<i>Meets the ANSI/AAMI EC13 Section 4.2.9. 12 standard: minimum = 0.2 mV RTI.</i>
Tall T-Wave Rejection Capability	Meets AAMI standard: 0.5 – 40 BW: HR of 80bpm at all T-wave amplitudes 0.05 – 40 BW: HR of 80bpm at all T-wave amplitudes

## Respiration

Parameter	Specification
Leads Used for Measurement	RA, LL (standard) or I, A (EASI)
Range	Adult/Pedi: 0 to 120 rpm
Bandwidth	0.3Hz to 2.5Hz (-6dB)
Noise	Less than 25 mOhm (rms) referred to the input
Calibration Signal	Signal: 1 Ohm p-p; Accuracy: +/- 20%
Respiration Rate Resolution	1 rpm
Respiration Accuracy	+/- 1 rpm for 0-120 rpm
Auxiliary Current, Respiration Excitation Signal	< 470 uA rms @48KHz, sinusoidal waveform

## Respiration Alarm

Alarm	Range	Delay
High	Adult/Pediatric: 10 to 100 rpm	≤ 15 seconds
Low	Adult/Pediatric: 0 to 95 rpm	for limits from 0 to 20 rpm: max. 4 seconds for limits above 20 rpm: max. 15 seconds
Apnea Alarm	10 to 40 seconds	Incremental delay 5 seconds max.

## Measurement Specifications

**FAST SpO<sub>2</sub>**

Parameter	Specification
SpO <sub>2</sub> Measurement Range (Calibration and Display)	0 to 100%
SpO <sub>2</sub> Accuracy	See table following.
SpO <sub>2</sub> Resolution	1%
SpO <sub>2</sub> Numerics - Averaging	<p>5 - 20 seconds (default = 10 seconds)</p> <p><b>Note</b>—The update rate for the SpO<sub>2</sub> pulse oximetry value and pulse rate is typically 1 second. This can be extended to a max. 60 s when NBP is measured on the same limb, with a corresponding INOP message after a max. of 30 s, indicating that the displayed values are not current values.</p> <p>The effect of SpO<sub>2</sub> pulse oximetry on data averaging is internally controllable by the patient worn monitorMX40, with no user controls.</p>
SpO <sub>2</sub> & Pulse Numerics - Update Rate	<p>Transmitted once per second.</p> <p><b>Note</b>—The update rate for the SpO<sub>2</sub> pulse oximetry value and pulse rate is typically 1 second. This can be extended to a max. 60 s when NBP is measured on the same limb, with a corresponding INOP message after a max. of 30 s, indicating that the displayed values are not current values.</p>
Pleth Wave- Sampling Rate	125 sps
Technical Alarms (INOPs)	Triggered if the sensor is disconnected, if a pulse is not detected, if the signal is noisy, if light interference is detected, if the sensor is defective, if the measurement is erratic, or if the module is malfunctioning
Wavelength Range	<p>500 to 1000 nm</p> <p><b>Note</b>—Information about wavelength range can be especially useful to clinicians (e.g., clinicians performing photodynamic therapy).</p>
Pulse Rate Measurement (available only with Continuous SpO <sub>2</sub> )	<p>Range: 30 to 300 bpm</p> <p>Accuracy: +/- 2%</p> <p>Resolution: 1 bpm</p>

Parameter	Specification
Display of SpO <sub>2</sub> numerics	SpO <sub>2</sub> values are displayed as xxx % SpO <sub>2</sub> to meet ISO 9919.
Emitted Light Energy	≤ 15 mW

## SpO<sub>2</sub> Sensor Accuracy

Type	Description	Model Number	Accuracy % <sup>A</sup> <sub>rms</sub> (70-100% Range)
<b>Reusable Sensors</b>			
	Adult Finger, 2m cable	M1191B	2.0
	Adult Finger, 3m cable	M1191BL	2.0
	Adult Finger, 0.45m cable	M1191T	3.0
	Pediatric, Small Adult Finger, 1.5m cable	M1192A	2.0
	Pediatric, Small Adult Finger, 0.45m cable	M1192T	3.0
	Adult & Pediatric Ear Clip, 1.5m cable	M1194A	3.0
	Adult Finger Clip, 3m cable	M1196A	3.0
	Adult Finger Clip, 2m cable	M1196S	3.0
	Adult Finger Clip, 0.9m cable	M1196T	3.0
	LNCS Adult Reusable Sensor	Masimo LNCS DC-I	2.0
	LNCS Pediatric Reusable Sensor	Masimo LNCS DC-IP	2.0
	LNCS Tip-Clip Ear Reusable Sensor	Masimo LNCS TC-I	3.5
	LNOP Adult Reusable Sensor	Masimo LNOP-DC-I	2.0
	LNOP Pediatric Reusable Sensor	Masimo LNOP DC-IP	2.0
	LNOP Tip-Clip Reusable Sensor	Masimo LNOP TC-I	3.5

Type	Description	Model Number	Accuracy % <sup>A</sup> <sub>rms</sub> (70-100% Range)
<b>Single Patient Use Sensors</b>			

## Measurement Specifications

Type	Description	Model Number	Accuracy % <sub>rms</sub> (70-100% Range)
	Adult Finger, > 40kg	M1901B	3.0
	Pediatric 3-20kg	M1902B	3.0
	Pediatric Finger, 10-50kg	M1903B	3.0
	Adult Finger, >30kg	M1904B	3.0
	Adult, Pediatric > 20kg	M1131A	3.0
	Adult Finger, > 30kg	Nellcor OxiMax Max-A	3.0
	Adult Finger, > 30kg	Nellcor OxiMax Max-AL	3.0
	Adult Finger > 40kg	Nellcor OxiMax Max-N	3.0
	Pediatric	Nellcor OxiMax Max-P	3.0
	Pediatric	Nellcor OxiMax Max-I	3.0
	Adult Finger > 30kg	Nellcor Oxisensor II D-25	3.0
	Adult Finger > 40kg	Nellcor Oxisensor II N-25	3.0
	Pediatric Finger 10-50kg	Nellcor Oxisensor II D-20	3.0
	Adult Finger	Nellcor OxiCliq A	3.0
	Pediatric Finger	Nellcor OxiCliq P	3.0
	Pediatric	Nellcor OxiCliq I	3.0
	Adult Finger > 40kg	Nellcor OxiCliq N	3.0
	Pediatric Adhesive	Masimo LNOP PDT	2.0
	Pediatric Adhesive	Masimo LNOP PDTx	2.0
	Adult Adhesive	Masimo LNOP ADT	2.0
	Adult Adhesive	Masimo LNOP ADTx	2.0
	Adult Adhesive	Masimo LNCS ADTx	2.0
	Pediatric Adhesive	Masimo LNCS PDTx	2.0

Measurement Specifications

Type	Description	Model Number	Accuracy % <sup>A</sup> <sub>rms</sub> (70-100% Range)
	Adult Adhesive	Masimo LNCS Neo-3	2.0



## A. Accessories

This section lists the accessories for use with the MX40. Accessories are subject to change. Some accessories are not supplied by Philips.

You can order parts and accessories from Philips at [www.medical.philips.com](http://www.medical.philips.com) or consult your local Philips representative for details.

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### Warning

- Use only Philips-approved accessories. Use of product accessories (patient cables, SpO<sub>2</sub> sensors, etc.) other than those specified in this manual may lead to patient injury or result in increased electromagnetic emissions or decreased immunity of the product.
  - Reuse: Never reuse disposable transducers, sensors, accessories, etc. that are intended for single use, or single patient use only. Reuse may compromise device functionality and system performance and cause a potential hazard.
  - Philips' approval: Use only Philips-approved accessories. Using non-Philips-approved accessories may compromise device functionality and system performance and cause a potential hazard.
  - Packaging: Do not use a sterilized accessory if its packaging is damaged.
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## MX40 Accessories

### Pouches

Order Number	Description
989803174141	Carry Pouch, Waterproof, box of 50
989803174151	Carry Pouch, Waterproof, box of 200
9300-0768-050	Disp tele pouch w/snaps, 50/box
9300-0768-200	Disp tele pouch w/snaps, 200/box

### Miscellaneous

Order Number	Description
989803176501	Protective caps, adapter cable, MX40
989803176491	Protective caps, Reusable leads, MX40
989803174131	MX40 Lithium-ion battery, pkg 3
989803176201	MX40 Lithium-ion battery, pkg 1
989803174891	MX40 AA Battery adapter, pkg 3
989803134771	Skin Preparation Sheets, 10 preps/sheet, pkg 10



## ECG Accessories

### Electrodes

Order Number	Description
M4612A	Solid gel ECG electrode disp. 5/pouch 300/case
M4613A	Solid gel ECG electrode disp. 30/pouch 300/case
40489E	Adult paper tape ECG electrode, disp. 300/case
40493D	Adult foam ECG electrode, disp. 300/case
40493E	Adult foam ECG electrode, disp. 300/case
M1935A	Disposable EEG/ECG snap electrode 100/case
989803148801	Small adult solid gel snap electrode 1500/case
13941E	Adult cloth ECG electrode, disp. 300/case
13942E	Adult plastic tape ECG electrode, disp. 300/case
13950B	Pediatric cloth ECG electrode, disp. 300/case
13951C	Neo/Pediatric solid gel electrode, disp. 300/case
13955C	Neo/Pedi snap electrode, square, disp.300/case

### Leadsets and Patient Cables

#### MX40 Reusable Patient Cables

Order Number	Description
989803171801	ECG 3 lead grabber AAMI .85m (35")
989803171811	ECG 3 lead grabber AAMI + SpO <sub>2</sub> .85m (35")
989803171821	ECG 5 lead snap AAMI .85m (35")
989803171841	ECG 5 lead snap AAMI + SpO <sub>2</sub> .85m (35")
989803171831	ECG 5 lead grabber AAMI .85m (35")
989803171851	ECG 5 lead grabber AAMI + SpO <sub>2</sub> .85m (35")

Order Number	Description
989803171861	ECG 6 lead grabber AAMI .85m (35")
989803171871	ECG 6 lead grabber AAMI + SpO <sub>2</sub> .85m (35")
MX40 Extender Cable, including Bed Sheet Clip, p/n 989803172241	

#### **MX40 Single-Patient-Use Cables**

Order Number	Description
989803172031	ECG 5 lead grabber AAMI .85m (35")
989803172051	ECG 5 lead grabber + SpO <sub>2</sub> AAMI .85m (35")
989803172131	ECG 5 lead grabber IEC 85m (35")
989803172151	ECG 5 lead grabber + SpO <sub>2</sub> IEC .85m (35")

#### **Reusable Leadsets for Use with IntelliVue Patient Monitors**

Order Number	Description
989803151991	ECG 3 lead snap, gray, AAMI .85m (35")
989803151971	ECG 3 lead grabber, gray, AAMI .85m (35")
989803152071	ECG 5 lead snap, multi AAMI .85m (35")
989803152051	ECG 5 lead grabber, multi AAMI .85m (35")
989803152001	ECG 3 lead snap, gray IEC .85m (35")
989803151981	ECG 3 lead grabber, gray IEC .85m (35")
989803152081	ECG 5 lead snap, multi IEC .85m (35")
989803152061	ECG 5 lead grabber, multi IEC .85m (35")
All above leadsets require the MX40 to IntelliVue Adapter Cable, p/n 989803172211 and the use of the 3 lead and 5 lead Detachable Shield when showering.	

## SpO<sub>2</sub> Accessories

### Philips/Nellcor Disposable Sensors

Order Number	Description
989803105481 (A)	M1904B Adult Finger, >30 kg
989803128551	M1133A Neo/Infant/Adult, <3, 10-20 kg, >40 kg
989803164921	M1134A Adh.-free Neo/Infant/Adult, >40 kg
989803128531	M1131A Adult/Pedi, >20 kg
989803111561(A)	M1903B Pedi Finger, 10-50 kg
989803105471(A)	M1902B Infant, 3-20 kg
989803105461(A)	M1901B Neonatal (adult application only), <3 kg, >40 kg
989801190969 (B)	NellCor OxiMax Max-1, 3-20 kg
989801190966 (B)	Nellcor Oxisensor II D-20, 10-50 kg
989801190967 (B)	Nellcor OxiMax D-25, >30 kg
989801190970 (B)	Nellcor OxiMax N-25, <3 kg, >40 kg
Require M1943A/AL cable to connect to MX40. Sold in packages of 24. (A) Only available from Philips in Europe and (B) Only available from Philips in Japan.	

### Philips Reusable Sensors

Order Number	Description
989803144371 A, B	M1191B Adult Finger, >50 kg
989803103231 A, B	M1192APedi/Sm. Adult 1.5 m, 15-50 kg
989803103251 A, B	M1194A Adult/Pedi Ear 1.5m, >40 kg
989803144381 A	M1191BL Adult Finger 3 m, >50 kg
989803128631 A	M1196A Adult Finger 3 m, >40 kg
989803128591 C, D	M1191T Adult Finger .45 m, >50 kg
989803128611 C, D	M1192T Pedi/Sm. Adults .45 m, 15-50 kg
989803128641 C, D	M1196T Adult Finger .9 m, >40 kg
989803174381 A, B	M1196S Adult Finger 2m, >40 kg

Order Number	Description
All sold as one piece each. A - Sensors plug directly into MX40. B - Supports use of M1941A extension cable. C - Not for use with M1941A extension cable. D - Requires M1943A/AL adapter cable.	

## Adapter Cables

Order Number	Description
989803105691	M1943A Adapter Cable, 1. m
989803128651**	M1943AL Adapter Cable, 3 m
989803105681**	M11941A Extension Cable, 2 m
M1020-61100**	Massimo Adapter Cable for LNOP sensors, 3.6 m
989803148221**	Massimo Adapter Cable for LNCS sensors, 3 m
**Not to be used with the MX40 extender cable, p/n 989803172241	

## B. Default Settings

This section documents the most important default settings of your MX40 as it is delivered from the factory. For a comprehensive list and explanation of default settings, see the *IntelliVue Information Center Release N Configuration Guide*. The MX40's configuration settings can be changed permanently in Configuration Mode.

## Alarm Default Settings

Alarm Setting	Factory Default
Alarm Volume	On Network: 0 Off Network: 10
QRS Volume	0
Tone Modulation	On
Alarm Sound	Traditional
Alarm Pause Time	2 min. <b>Note</b> — The Alarm Pause Time when operating with Information Center Release L or M is not configurable. It is always 2 min.
Alarm Reminder (Red, Yellow)	On
Alarm Reminder (INOP)	On
Reminder Time	3 min.
ECG Leads Off - Severity	Cyan
Replace Battery - Severity	Cyan
Alarms On	Information Center Release L/M: Disabled Information Center Release N: Enabled

## ECG, Arrhythmia, ST and QT Default Settings

ECG Settings	Factory Defaults	
	Adult	Pedi
ECG	On	
Primary Lead	II	
Secondary Lead	6-lead: III 5-lead (Standard): III 5-lead (EASI): III	
Default ECG Size	x1	
Lead Placement	Standard	
Leadset Type	AAMI	
Analysis Mode	Multi-lead	
High Limit	120 bpm	160 bpm
Low Limit	50 bpm	75 bpm
Asystole Threshold	4.0 sec	

Arrhythmia Settings	Factory Defaults	
	Adult	Pedi
Arrhythmia	On	
Pause Threshold	2.0 sec	
VTach HR	100 bpm	120 bpm
VTach Run	5	
Vent Rhythm	14	
SVT HR	180 bpm	200
SVT Run	5	
PVCs/min	10	5
Non-Sustained VT	On	
Run PVCs	On	
Pair PVCs	On	
R-On-T PVCs	On	

Arrhythmia Settings	Factory Defaults	
	Adult	Pedi
V.Bigeminy	On	
V.Trigeminy	On	
PVCs/min	On	
Multif. PVCs	On	
Pacer N. Cap	On	
Pacer N. Pac	On	
Pause	On	
Missed Beat	On	
SVT	On	
Afib	On	
Irregular HR	On	



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## Configuration Default Settings at the MX40

Setting	Factory Default
Touch Tone Volume	0 - 10 <b>4</b>
Default Screen	1 Wave (Portrait) <b>2 Waves (Portrait)</b> 2 Waves (Landscape) Chest Diagram
Screen Color	<b>Blue</b> Gray Green Pink* Purple* Yellow* (*only display in Standby Mode)
Alarm Sounds	<b>Traditional</b> ISO
Unit Defaults	Confirm to restore to unit default settings



## C. Sales and Support Offices

Please call your local Philips Healthcare sales office listed in your telephone directory or a Philips Healthcare regional office listed below for the location of your nearest sales office.

*On the web*

**[www.healthcare.philips.com](http://www.healthcare.philips.com)**

*Via email*

**[healthcare@philips.com](mailto:healthcare@philips.com)**

*By fax*

**+31 40 27 64 887**

*By postal service*

**Philips Healthcare  
Global Information Center  
P.O. Box 1168  
5602 BD Eindhoven  
The Netherlands**

*Asia*

Tel: +842 2821 5888

*Europe, Middle East, Africa*

Tel: +31 40 27 63005

*Latin America*

Tel: +55 11 2125 0764

*North America*

Tel: +1 800 229 6417



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# **EXHIBIT 2**

## Dear *LifeWatch V* owner:

Thank you for selecting the *LifeWatch V* mobile medical phone.

This user manual includes information and instructions for using your new *LifeWatch V* device. Please read this manual carefully before you start using the device.

If you have any questions about your *LifeWatch V*, please contact your representative:



Illustrations included in this manual are general representations only and are not meant to comply with specific regulatory requirements.

By default, your phone is provided with pre-set applications.

Installation of new applications may affect the performance of your phone and is the sole responsibility of the user.



Before using the *LifeWatch V* medical and wellness functions please read the Warnings and Precautions, Appendix A, thoroughly.

## Copyright Declaration

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For self-testing

2

#### LifeWatch V Kit Contents

- ◆ *LifeWatch V*
- ◆ Adapter
- ◆ Earphones
- ◆ User manual
- ◆ Quick user guide
- ◆ USB cable

#### Optional – LifeWatch V Gluco Accessories Kit Contents

- ◆ 1 lancing device
- ◆ 10 lancets
- ◆ Gluco strip vial
- ◆ Control solution
- ◆ 10 Alcohol pads
- ◆ Disinfection pads
- ◆ Gluco strip Quick user guide
- ◆ Lancer Quick user guide

#### Contraindications

In order to use this device, you must be able to:

- Understand the operation principles as described in this manual
- Operate a *LifeWatch V* and the *LifeWatch V* Application
- Operate a touch screen

#### **General contraindications for all medical modules:**

- The *LifeWatch V* is not intended for use by persons with external defibrillators
- The *LifeWatch V* is not intended for the treatment or alleviation of disease
- The *LifeWatch V* is not to be used in a magnetic resonance imaging (MRI) environment

**Warning:**








- Do not expose the unit to rain or moisture
- Servicing of the device shall be done by qualified personnel only
- The user of the *LifeWatch V* should not take any actions of a medical or clinical nature based on his/her understanding or interpretation of test results without consulting a healthcare professional.
- Classifications of test results obtained for medical modules or for wellness applications into categories such as “Low”, “Normal”, “Average”, etc. are based on well-established and widely accepted clinical sources; as other classifications may exist, the test results should not constitute the sole basis for diagnosis or for deciding on the appropriate course of medical treatment or therapy.







## Important Symbols

A number of symbols are used throughout this manual in order to draw attention to safety items and other important information.

***Symbols on Equipment and Labeling***

The following section contains a description of symbols that may be located on either the equipment or the documentation.

Label	Description
	Warning, consult accompanying text or documents
	Precaution; consult accompanying text or documents
	Warning, potential biohazard
	Notes, indicates important general information for using the system successfully.
	Consult instructions for use
 XXXX	Manufacturer and date of Manufacture
	Type BF Applied Part

Label	Description
	In vitro device
	Store at specified temperatures; location of thermometer
	WEEE Directive for disposal of Electrical and Electronic Equipment
	Symbol for no alarms
	Symbol indicating a USB connector
	Symbol indicating location of glucose meter

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#### WARNINGS

- Use the device only for the purposes described in the instructions for use.
- To prevent fire, do not expose the device to moisture or excessive heat. Refer servicing to qualified personnel only.
- Do not use this device if it is not working properly, or if it has suffered any damage.

#### WARNING

Device not suitable for use in the presence of flammable anesthetic mixture with air or with Oxygen or Nitrous Oxide.

#### WARNING

- For optimal use of the LifeWatch V it should be connected to the Internet.
- By default, your phone is provided with pre-set applications.
- Installation of new applications may affect the performance of your phone and is the sole responsibility of the user.”

#### WARNING

The user of the *LifeWatch V* should not take any actions of a medical or clinical nature based on his/her understanding or interpretation of test results without consulting a healthcare professional.

## Intended Use

The *LifeWatch V* is a medical device designed for self-testing in order to measure and display blood oxygen saturation, blood glucose, ECG (1 lead), heart rate, body fat percentage, stress level analyzer and body temperature. The *LifeWatch V* is intended for use in the following population groups:

- Adults
- Pediatrics as defined per medical module

The following applications of the *LifeWatch V* as described in this User Manual, are not within the scope of the Medical Device Directive 93/42/EEC and are therefore not considered as medical devices, nor are they covered by the this Directive:

- Stress Level Analyzer
- Drug Management
- Body Fat Analysis
- Diet Management

Test	Age Group
Pulse oximeter	Adults, 21 years and older
Blood Glucose meter	Adults and pediatrics above 12 years Pediatrics below the age of 12 years: under adult supervision only Excluding neonates and infants less than one year
1 Lead ECG	Adults and pediatrics above 12 years of age
Heart Rate	Adults and pediatrics above 12 years of age
Stress Level Analyzer	Adults, 21 years and older

Body Fat Analyzer	Adults, 21 years and older
Thermometer	Adults and pediatrics above 12 years Pediatrics below the age of 12 years: under adult supervision only Excluding neonates and infants less than one year

#### Device Definition

The *LifeWatch V* is a state-of-the-art mobile device (smartphone) with medical and non-medical capabilities designed for the maximum convenience of its users. The *LifeWatch V* includes the following modules and applications:











- Pulse oximeter/SpO2 (oxygen saturation)
- Blood Glucose meter
- 1 Lead ECG
- Heart Rate
- Thermometer
- Body Fat Analyzer
- Stress Level Analyzer
- Diet Management
- Drug Management








**NOTE:** The *LifeWatch V* can be used as a stand-alone device or via a subscription plan; full functionality is available only to paying subscribers.

## LifeWatch V Basic Operation

### For Your General Safety (Precautions)

As the *LifeWatch V* device is a medical device that can be used both as a regular cell phone and as a medical device, this manual includes both warnings and precautions relating to the use of the *LifeWatch V* as a cell phone, AND warnings and precautions concerning the use of the *LifeWatch V* as a medical device.

	Do not make or receive handheld calls while driving; do not text while driving.		Keep the device away from pacemakers, ICDs and other electronic medical devices (at least 6 inches/15 cm).
	Don't use the device at gas/petrol stations.		Do not expose the device to extreme temperatures.
	Keep your phone at least 15 mm away from your ear or body while making calls.		Switch the device off when asked to in hospitals and medical facilities.
	Your phone may produce a bright or flashing light.		Avoid contact with liquids. Keep your phone dry.
	Small parts may cause choking.		Switch the device off when told to in aircrafts and airports.

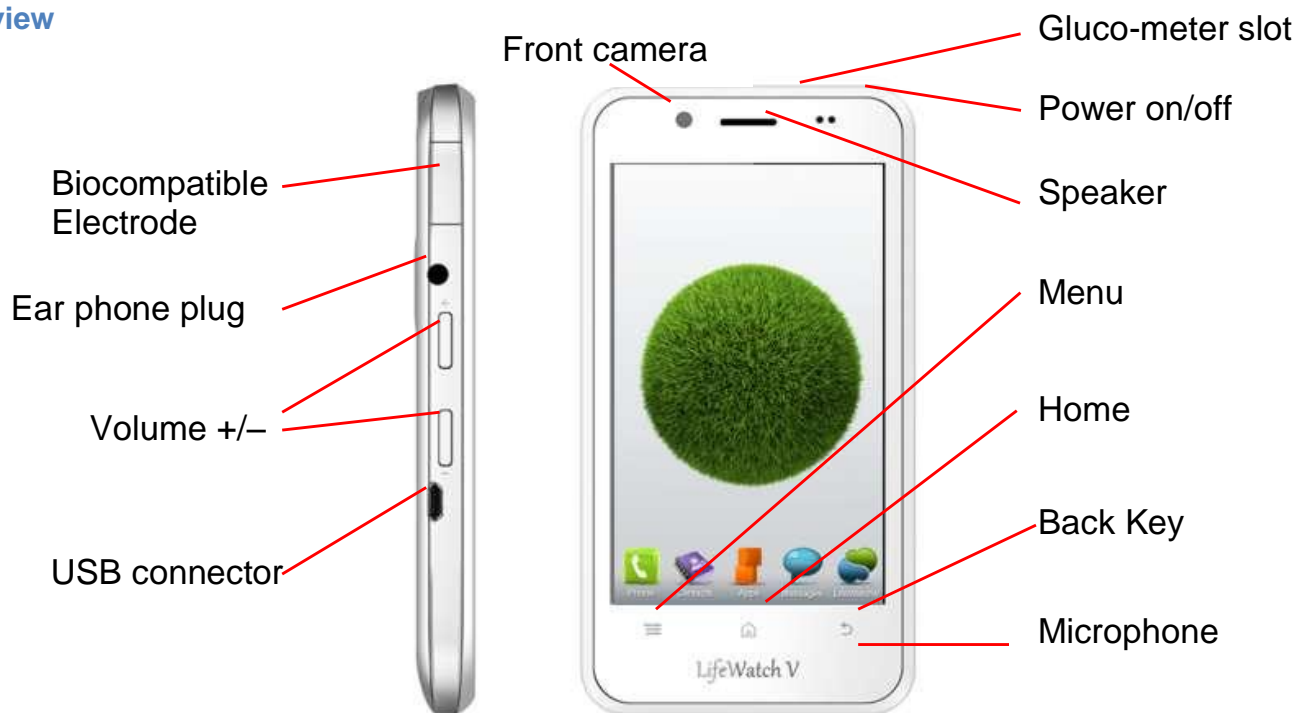
	Don't dispose of your device in fire.		Don't take your device apart.
	Your device can produce a loud sound.		Switch your device off when near explosive materials or liquids.
	Avoid contact with anything magnetic.		Only use approved accessories.
	Don't rely on your device for emergency communications.		

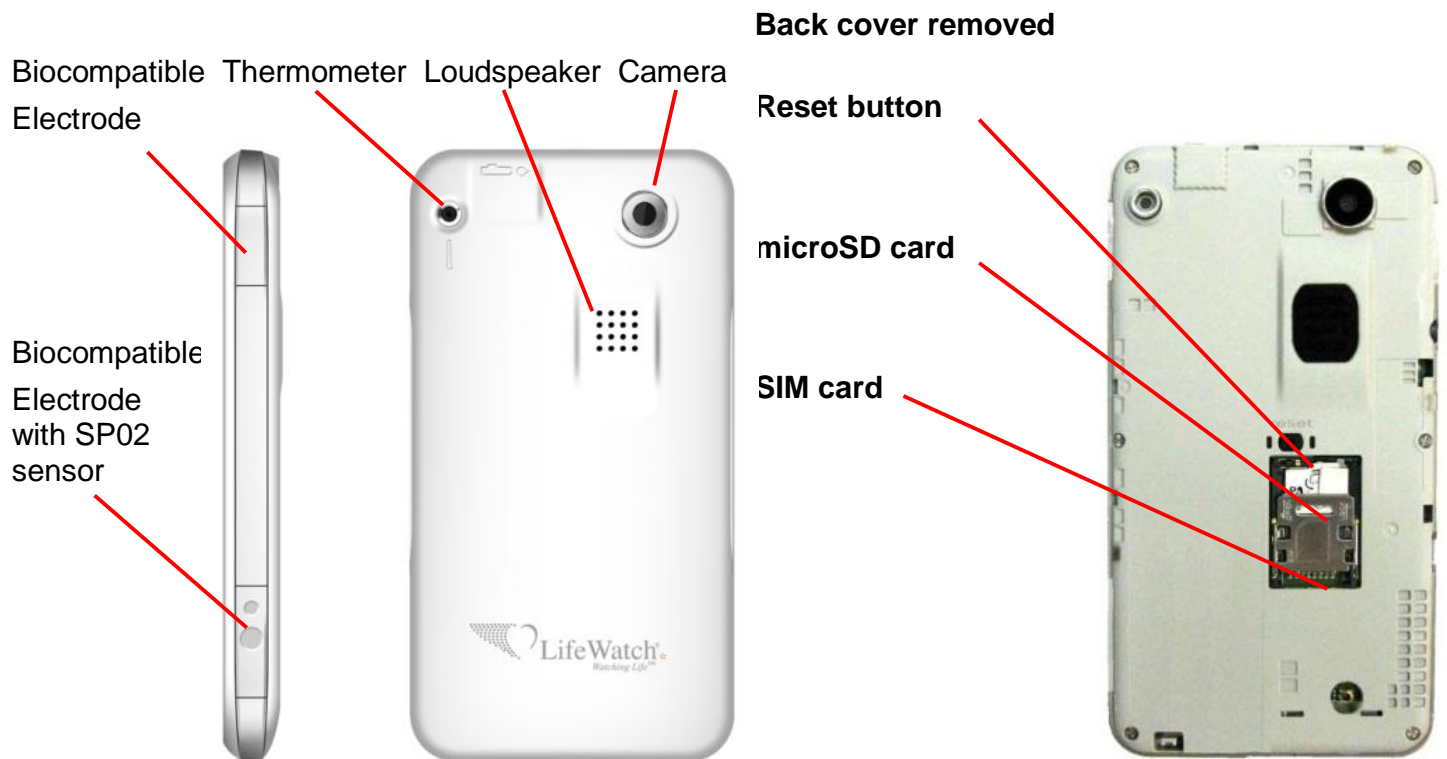


Before using the *LifeWatch V* medical and wellness functions please read Appendix A Warnings and Precautions thoroughly.

## Getting Started

### Overview







## Icons



LifeWatch V icon



Call icon



Contacts icon



Messages icon



Applications icon

## Keys Explained

Key	Function
Power	<ul style="list-style-type: none"> <li>• Hold to turn on or off Silent or Airplane mode, or to power off.</li> <li>• Press to switch your device to Sleep mode.</li> <li>• Press to wake up your device.</li> </ul>
Home	<ul style="list-style-type: none"> <li>• Press to return to the Home Screen from any application or screen.</li> <li>• Hold to see recently used applications.</li> </ul>
Menu	Press to get the options for the current screen.
Back Key	Press to go to the previous screen.
Volumes	Press or hold to turn the volume up or down.

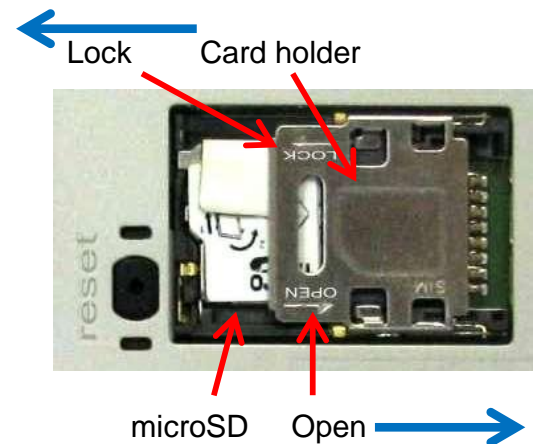


## Starting up

### ***Installing the SIM/microSD Card***


Switch off your device before installing, SIM, or memory card.

1. Remove the back cover.
2. Open the SIM card holder by sliding it in the direction of the OPEN arrow.
3. Hold the SIM card by the cut corner and slip it into the card holder.
4. Pull the microSD cover tag.
5. Hold your microSD card with the metal contacts facing down and slide it in.
6. Press the microSD cover down.
7. Press the SIM card holder gently back into place, sliding it in the direction of the LOCK arrow, until you hear a click.



### ***Removing the SIM/microSD Card***

1. Switch off your device.
2. Remove the back cover.
3. Open SIM card holder by sliding it in the direction of the OPEN arrow.
4. Slide the SIM card out.
5. Pull the microSD cover tag.
6. Slide the microSD card out.
7. Press the microSD cover down.
8. Press the SIM card holder gently back into place, sliding it in the direction of the LOCK arrow, until you hear a click.

**NOTE:** microSD logo  is a trademark of the SD Card Association.

## Charging the Battery

1. Connect the supplied USB cable's micro USB plug to the LifeWatch USB/adaptor jack. Ensure that the plug is inserted with the correct orientation. Do not force the plug into the jack.



USB input is 5 VDC: maximum 5.25VDC to minimum 4.75VDC at 1.7A max.

2. Connect the USB cable's USB plug to the adapter.
3. Connect the adapter to a standard AC wall outlet.
4. Disconnect the adapter when the battery is fully charged.


**NOTE:** When you first receive your device you will need to charge the battery for 12 hours with the device turned off.



Use only the supplied adaptor with the LifeWatch V.  
Input is 100 to 240 V, ~50 to 60 Hz, 0.3A;  
Output is 5 V, 0.7A, 3.5 W maximum

### ***How much charge is in the battery?***

If the battery is low, there will be a message on the screen. As you charge your device, the screen tells you the exact battery level each time you wake up your device.

If the device is on, you can see a charging icon on the status bar. As soon as charging is finished, this icon  appears on the status bar.

### ***Switching Your Device On/Off***

- ◆ Hold Power to switch on your device.
- ◆ To switch it off, hold Power to get the device options. Select Power off, and then tap OK.

Always place the adapter in easily accessible main plugs.



In case of electrical malfunction of device during connection to adapter, remove adapter from main plug immediately.

### ***Setting Up Your Device for the First Time***


When you first turn on your device after you purchase it or after resetting it to factory settings, the following should be performed:

1. If the default language needs to be changed, tap Change language and select the language you want to use.
2. Tap the Android icon on the screen.
3. Configure the date and time options, and then tap Next.

### ***Switching to Sleep Mode***

To save battery power, Sleep Mode suspends your device setting it to a low-power-consumption state while the display is off. Your device also goes into Sleep Mode by itself when the display is automatically turned off after a certain amount of time. You can define the period of time in **Settings > Display > Screen timeout**. Press Power to switch to Sleep Mode.

### ***Waking Up Your Device***

1. Press **Power** to activate your screen display.
2. Drag the  icon to the right.

**NOTE:** If you have set an unlock pattern, PIN or password for your device you'll need to draw the pattern or enter the PIN/password to unlock your screen.

## **Getting Around Your Device**

---

### **Touch Control**

You can use finger gestures to control your device. The controls on your touchscreen change dynamically depending on the tasks you're performing.

1. Tap the buttons, icons, or applications to select items or to open applications.
2. Keep your finger on an item to see the available options.
3. Flick the screen to scroll up, down, left or right.
4. Point, drag and drop to move particular items across the screen.
5. Pinch with two fingers or double-tap the screen to zoom in/out on a web page or an image. **NOTE:** You can view the device screen in portrait or landscape orientation simply by holding it upright or turning it on its side. Not all screens are viewable in landscape.

## Home Screen

You can modify your *Home* Screen.

Set your own wallpaper, add the widgets or application shortcuts you need, or remove them as you like.

### ***Extended Home Screen***

The *Home* Screen extends beyond the screen width, giving you lots more space to add more stuff. Simply slide your finger to the left or right to see the extended *Home* Screen.

### ***Changing Your Wallpaper***



1. Tap **Home** to return to the *Home* Screen.
2. Tap **Menu** and select **Wallpaper**.
3. Tap **Gallery**, **Live wallpaper**, or **Wallpaper** and choose the image or animation you want to use as the wallpaper. Some cropping may be needed for **Gallery** images.
4. Tap **Save** or **Set wallpaper**.



### ***Adding Items to Your Home Screen***


































1. Tap **Home** to return to the *Home* Screen.
2. Slide left or right to find a part of the *Home* Screen with free space.
3. Tap **Menu** and select **Add**.
4. You can also tap and hold the blank area of the *Home* Screen until the **Add to Home screen** menu is displayed.
5. Select a category, either shortcuts, widgets, or folders.
6. Choose the item you want to add to the *Home* Screen.



















### ***Removing Items from Your Home Screen***

1. Tap **Home** to return to the *Home* Screen.
2. Tap and hold the item you want to delete until the trash can  appears on the screen.
3. Drag the item to the trash can .



## Status and Notification Icons

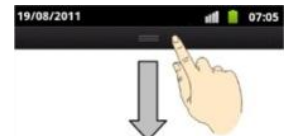
	GPRS connected		No signal		Connected to a Wi-Fi network
	GPRS in use		Signal strength		New Wi-Fi network detected
	EDGE connected		Phone speaker off		Portable Wi-Fi hotspot is on
	EDGE in use		Phone microphone off		Airplane mode
	3G connected		No SIM installed		Call in progress
	3G in use		GPS on		Call on hold
	Roaming		Error or warning		Call forwarding
	USB connected		Recording phone call		Missed call
	Battery flat		microSD card removed		USB tethering is on
	Battery very low		Preparing microSD card		Sending data
	Battery low		Battery full		Content downloaded and installed successfully

	Battery partially drained		Battery charging		Downloading data
	Vibrate mode		Wired headset		Song is playing
	Syncing		Bluetooth on		Bluetooth connected
	New mail		Speaker on		Alarm set
	New MMS		Upcoming event		New SMS
	Problem with SMS/MMS delivery		ECG result notification icon		Reminder notification icon

### ***Using the Notification Panel***

Flick the status bar downwards from across the top of the screen to open the *Notification Panel*, where you can see your calendar events, new messages, and current settings – such as call forwarding or call status.


**TIPS:** You can also open the *Notification Panel* by tapping **Menu > Notifications** from the *Home Screen*.



## Applications and Settings

---


### ***Applications***

Your device has lots of functions such as shown below. Tap  to see the following.

<b>Applications</b>	<b>Benefit</b>
Browser	Browse the Internet.
Calculator	Do basic calculation.
Calendar	Schedule appointments and events.
Camcorder	Shoot video clips.
Camera	Take pictures.
Contacts	Manage your contacts information.
Email	Send and receive Emails.
File Manager	Manage files on your device and microSD card.
FM Radio	Search for, listen to, and save radio channels (needs earphone).
Gallery	Manage multimedia files.
Messaging	Send and receive SMS and MMS messages.
Music	Browse your audio files and listen to them.
Places	Find restaurants, ATMs, and other businesses or attractions near you.

Search	Search for information online or on your device.
Settings	Adjust device settings.
SIM Tool Kit	Appears if your SIM card provides this function.
Sound Recorder	Capture audio clips.
Videos	Browse and watch video files.

## Settings

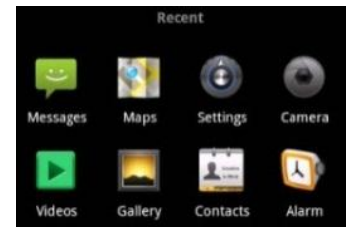
To change or view your device's settings, tap **Home** >  > **Settings** or from the *Home* Screen tap **Menu** > **Settings**.

Wireless & networks	Configure and manage wireless connections, such as Wi-Fi, Bluetooth®, mobile networks, mobile data connection sharing, and Virtual Private Networks.
Call settings	Set up fixed dialing numbers, voicemail, speed dial, call blocking, call forwarding, call waiting, caller ID, and Internet call settings.
Sound	Set sound settings, such as ringtones and notifications.
Display	Set display settings, such as screen brightness.
Location & security	Create you screen unlock pattern, set a SIM card lock, or manage the device's credential storage. You can also select the sources to use when determining locations from My Location.

Applications	Manage your applications.
Accounts & sync	Manage your accounts and configure synchronization settings.
Privacy	Configure privacy settings, such as back-up and restoration, and personal data.
Storage	Check available memory on the external card and on the internal device storage.
Language & keyboard	Set operating system language, region and text input options.
Voice input & output	Set up voice recognition and text-to-speech options.
Accessibility	Set up accessibility options after installing accessibility-related applications.
Date & time	Set the date, time, time zone, and date/time format.
About phone	View device status, battery use, and legal information. You can also check for system updates.

### ***Opening Recently-Used Applications***

1. Hold **Home** from any screen. The device displays application icons you have recently used.
2. Tap the application you want to open.





## Phone Calls

---

### Dialer Screen






This screen is used for phone call actions.

Tap  or  on the *Home* Screen to open the dialer.

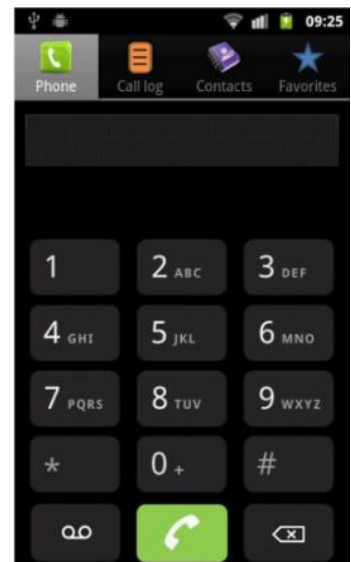
You can select dialing, check voicemail, view call log, contacts and favorite numbers.

### Making Calls





#### *Calling from the Dialer*

1. Tap  on the *Home* Screen or tap **Home** >  > **Phone**.
2. Enter the phone number with the on-screen keypad. Tap  to delete wrong digits.
3. Tap  to initiate the call.
4. Tap  to dial to your voicemail.






**TIPS:** To make international calls, hold  to enter the “+”.



### ***Calling from Your Contacts***




1. Tap  on the *Home* Screen or tap **Home** >  > **Contacts**.
2. Slide your finger to scroll the contacts list and tap the contact you want to call. You can search for a contact by tapping  on the bottom of the screen.
3. Tap  to initiate the call.

### ***Calling from Your Call History***

1. Tap  or  on the *Home* Screen, select call log  or **Home** >  > **Call log**.
2. Tap  next to the number you want to call.

### ***Calling from a Text Message***

You can make the call while viewing the text message.

1. Tap  on the *Home* Screen or **Home** >  > **Messaging**.
2. Tap the conversation and then the message that contains the phone number you need.
3. Tap the number.
4. Tap  to initiate the call.

## Call Screen

This appears during a call, you are able to perform the following:

Dialpad - Open dialer

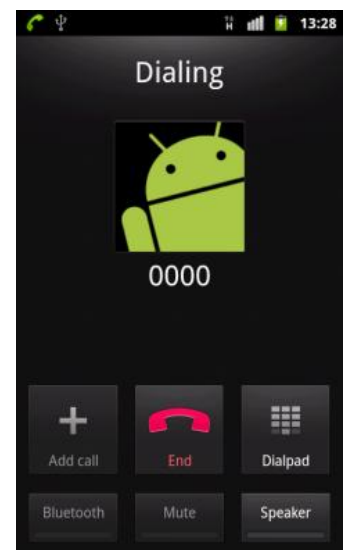
End call

Add call (conference call)

Speaker – switch between speaker and loud speaker

Mute – turns off the device microphone


Bluetooth – connects to a Bluetooth handsfree or earphone device

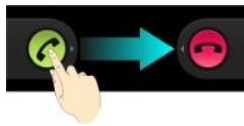





## Receiving Calls

### **Answering a Call**

Drag  to the right to answer the call.




### **Rejecting a Call**

Drag  to the left to reject the call.

### **Muting a Call**

During a call, you can mute your microphone so that the person you are speaking to cannot hear you, but you can still hear them:


Tap **Mute** to turn your microphone off. The mute icon  appears on the status bar. To turn your microphone back on, tap **Mute** again.

### **Putting a Call on Hold**


During a call, you can place it on hold by tapping **Menu > Hold**. The  icon appears on the screen.

**TIPS:** If you accept an incoming call while you're on another call, the first call is automatically placed on hold. Just tap **Menu > Swap calls** to switch between the two callers.

### ***Turning the Speakerphone On/Off***

Tap **Speaker** during a call to turn the speakerphone on. This icon  appears in the status bar. Tap **Speaker** again to turn off the speakerphone.

### ***Ending a Call***

Tap  to finish a call.



### ***Adjusting Your Call Settings***

From the *Home* Screen, you can open the call settings menu by tapping **Menu > Settings > Call settings > Call Feature Settings**.

Fixed dialing numbers	Restrict outgoing calls to a fixed set of numbers. To do this you must know your SIM's PIN2 code.	
Voicemail service	Select a voicemail service provider.	
Voicemail settings	Specify a voicemail number.	
Call forwarding	Forward your incoming calls to a different number. And choose when to forward: Always forward; Forward when busy; Forward when unanswered, or Forward when unreachable.	
Additional settings	Caller ID	Choose whether people you call can see your number.
	Call waiting	See new incoming calls while you're on another call.
Accounts	Set up Internet calling (SIP) accounts.	
Use Internet calling	Choose when to use the Internet calling function.	

## Contacts

You can add contacts to your device and synchronize them with the contacts in your account that support contact syncing.

To see and edit your contacts, tap  on the *Home* Screen or **Home** >  > **Contacts**.

## Importing and Exporting Contacts

You can import or export contacts from/to your SIM card or microSD card. This is especially useful when you need to transfer contacts between different devices.

Importing Contacts from the SIM Card or Exporting to the Card

1. Tap **Menu > More > Import/Export** from the *Contacts* Screen.
2. Choose **Import from SIM card** or **Export to SIM card**. Your device automatically displays the contacts.
3. Tap the contacts you want to import or export.  
Or, just tap Menu > Select all.
4. Tap OK.

## Importing/Exporting Contacts from/to the microSD Card

1. Tap **Menu > More > Import/Export** from the *Contacts* Screen.
2. Choose **Import from SD card** or **Export to SD card**.

- ◆ For import, you should have vCard files saved in the microSD card. If there's more than one vCard file, you need to select the vCard file and tap **OK**.
- ◆ For export, the device will prompt you with the name of the vCard file. Tap **OK** to create the file on the microSD card.

### ***Sharing Contacts Information***

1. Tap **Menu > More > Import/Export > Share visible contacts** from the *Contacts* Screen. Your device will export all the information for the contacts listed in the *Contact* Screen to a temporary vCard file.
2. Choose how you want to send the vCard file. You can send it via Bluetooth, mail or messages.

### ***Creating a Contact***


1. Tap **Menu > New contact** from the *Contacts* Screen.
2. Enter the **Contact Name**, **Phone** numbers, and other information.
3. Tap **Done** to save the contact.

### ***Adding a Contact to Favorites***

1. In the *Contact* Screen, tap and hold the contact you want to add to **Favorites**.
2. Tap **Add to favorites** from the pop-up menu.

**TIPS:** You can also tap a contact and then tap  next to the contact's name to add it to **Favorites**.

### ***Searching for a Contact***

1. Tap **Menu > Search**  at the bottom of the *Contacts* Screen.
2. Input the name you seek. The matching contact(s) are listed.

### ***Creating a New Group***

1. Tap **Menu > More > Group** Management from the *Contacts* Screen.
1. Tap **Menu > New Group**.
2. Enter the group name and tap **Done**.
3. Tap **Add Member**.
4. Tick the check boxes next to the contacts you want. Then tap **OK**.

To send messages to the group members, you can tap the group and select message recipients from the listed group members.

### **Entering Text**

When you need text or numbers, a keyboard automatically appears on the screen. You can also press the **Back Key** or hold **Menu** to hide the onscreen keyboard.

### **Android Keyboard**


The Android Keyboard provides a layout similar to a desktop computer keyboard. Turn the device sideways and the keyboard will change from portrait to landscape.









In order to select the keyboard type, hold the input box and select **Input method** from the pop-up menu to change the input method.



To use the landscape keyboard, just tick the **Auto-rotate screen** check box in **Settings > Display**. (The landscape keyboard is not supported in all applications.)





- Tap the alphabetic keys to enter letters. Tap and hold some specific keys to enter

associated accented letters or numbers. For example, to enter È, tap and hold  and the available accented letters and number 3 appear. Then slide to choose È.

- Tap  to use uppercase or lowercase. This key also changes to indicate the current case you are using:  for lowercase,  for uppercase, and  when locked in uppercase.
- Tap  to delete the text before the cursor.
- Tap  to select numbers and symbols. Tap  to see more choices. Often used symbols are displayed on top of the keyboard. Flick left or right to find the digit/symbol you need and tap to enter.
- Tap  to enter a smiley face; hold the key and swipe to choose more emoticons.

- Tap  to change input method or to set up the Android keyboard.
- Tap  to use Google's networked voice input.

## Messaging



Your SMS (text message) and MMS (multimedia messaging service) are combined into one menu, tap  on the *Home* Screen or **Home** >  > **Messaging**.

### ***The Message Box***

All your messages both those you have sent and those you have received are located in the Message box. *Messages* with the same number are grouped into a single thread in the *Messages* Screen. You can tap a thread to see the conversation you have had with someone.

Message threads are sorted in chronological order with the newest message on top.

### ***Sending a Message***

1. Tap  on the *Home* Screen or **Home** >  > **Messaging**.
2. Tap **New message**.
3. Enter the recipient's number or name. As you type, matching contacts appear. Tap a suggested contact to add as a recipient.

4. Tap **Type to compose** and type your message.

- ◆ Tap **Menu** to insert Quick Text, signature, smiley, or contact.
- ◆ If you are sending an MMS, tap **Menu** to add a subject, or attach pictures, videos, audios, or slideshows.

5. Tap **Send** to send your message.

**NOTE:** When you add an attachment to a text message it is automatically converted into an MMS. Likewise if you remove all attachments and the subject from an MMS, it automatically becomes a text message.

### ***Messaging Settings***

The device's message settings are pre-configured for your immediate use. To change them, tap **Menu > Settings** from the *Messaging* Screen.

#### **Storage settings:**

- ◆ **Delete old messages:** Select to delete old messages when you reach your storage limits.
- ◆ **Text message limit:** Set the maximum number of text messages allowed in a single thread.
- ◆ **Multimedia message limit:** Set the maximum number of multimedia messages allowed in a single thread.

#### **Text message (SMS) settings:**

- ◆ **Delivery reports:** Request a delivery report for every text message you send.



- ◆ **Manage SIM card messages:** Manage the messages saved to your SIM card.

#### **Multimedia message (MMS) settings:**

- ◆ **Delivery reports:** Request a delivery report for every MMS message sent.
- ◆ **Read reports:** Request a read report for each MMS message sent.
- ◆ **Auto-retrieve:** Automatically retrieve MMS messages.
- ◆ **Roaming auto-retrieve:** Automatically retrieve MMS messages when you're roaming.

#### **Notification settings:**

- ◆ **Notifications:** Show message notifications in the status bar.
- ◆ **Select ringtone:** Choose a ringtone for your incoming messages.

**Vibrate:** Make your device vibrate when a new message arrives.


#### **Cell Broadcast:**

- ◆ **GSM/UMTS Cell Broadcast:** Configure GSM/UMTS CB messages.

**NOTE:** Tap **Menu > Restore default settings** to change all the message settings back to the original.

## **Email**

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Tap **Home** >  > **Email**. use the *Email* Screen to setup your Email account and to exchange Emails.

## Creating an Email Account

1. When you open **Email** for the first time, enter your **Email address** and **password**. Then tap **Next**.
2. Select your account type and tap **Next**.
3. Edit the settings for the incoming server and the outgoing server. Tap **Next**. Your device will connect to the Internet and verify the settings before proceeding to the next step. Please contact your mobile service provider and Email service provider for additional help.

**NOTE:** Your device knows the client settings for many Email service providers. If the Email you use is from those providers, the device will automatically configure the incoming and outgoing settings after you enter your Email address and password.

4. Set the **Email checking frequency, download options, account name** and other settings. Tap **Done** when you finish.

Your Email account's inbox appears and the device will download your Email messages.

**TIPS:** To add more **Email** accounts, open Email to get the Inbox screen. Then tap **Menu > Accounts > Menu > Add account**.

## Receiving Emails

Press **Menu > Refresh** to download recent Emails. Select **Load more messages** located at the bottom of the Email list to download earlier messages.

## Composing and Sending an Email

After creating an Email account, you can compose and send Email messages.

1. Tap **Menu > Compose** from the *Inbox* Screen.
2. Tap **To** and enter the recipient's address. When you start to enter an address, auto-complete suggests matching contacts. Select one or more. Separate each recipient with a comma.

**TIPS:** You can also tap **Menu > Add Cc/Bcc** to add more recipients.

3. Enter the subject and the content of your Email. If necessary, change the email priority. Tap **Menu > Add attachment** to add files to the Email.
4. Tap **Send**.

## Replying to or Forwarding an Email

1. Open the Email you want to reply to or forward in the *Inbox* Screen.
2. Tap **Reply** to start a reply or **Menu > Forward** to reply to/forward the Email. You can also tap **Reply all** to reply to all the email's recipients.
3. Enter/edit the contents/recipients of your Email.
4. Tap **Send**.

### ***Deleting an Email Account***

1. Open the **Email** application. If there is only one account, tap **Menu > Accounts** to get the **Accounts** list.
2. Tap and hold the account you want to delete and select **Remove account** from the pop-up menu.
3. Tap **OK** to confirm.


### ***Email Settings***

Tap the account you want to configure in the *Accounts* Screen and tap **Menu > Account settings**. You can obtain the settings for the Email account. You can also tap **Menu > System settings** to set up storage, exchange and other settings.

### **Getting Connected to the Internet**


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Your device's impressive networking capabilities allow you to access the Internet or your corporate network with ease. You can use the default connection settings to connect to the Internet via your mobile network (GPRS/EDGE/3G), or via Wi-Fi.

The GPRS/EDGE/3G connection can be enabled/disabled manually. Just select **Home >  > Settings > Wireless & networks > Mobile networks** from the *Home* Screen and select or clear the **Data enabled** check box.

### Adding a New GPRS/EDGE/3G Connection


To connect via GPRS/EDGE/3G you need a data plan with your service provider. Also if the GPRS/EDGE/3G settings are not pre-configured on your device, please contact your provider to get the necessary information.

1. Tap **Home** >  > **Settings** > **Wireless & networks** > **Mobile networks** > **Network Settings** > **Access Point Names**.
2. Tap **Menu** > **New APN**.
3. Tap each item to enter the information you received from your service provider.
4. Tap **Menu** > **Save** to complete.


**TIPS:** To set the APN to default settings, tap **Menu** > **Reset to default**.

### Turning On Wi-Fi

Wi-Fi provides wireless Internet access.

1. Tap **Home** >  > **Settings** > **Wireless & networks**.
2. Tick the **Wi-Fi** box to turn it on.

### ***Connecting to a Wi-Fi Network***

1. Tap **Home** >  > **Settings** > **Wireless & networks** > **Wi-Fi settings**.  
The Wi-Fi access points, or “hotspots”, that your device has detected are displayed with their names and security settings.
2. Tap an access point to form a connection.  
If security features are implemented, you’ll need to enter a password.

### ***Checking the Wi-Fi Network Status***

You can check the Wi-Fi network by looking at the  icon in the status bar.

Or tap the access point that the device is currently connected to in **Wi-Fi settings**. You can then check the network status from the pop-up window.

### ***Using the Device as a Wi-Fi Hotspot***

You can use the device as a portable WLAN router, providing Wi-Fi connection for one or multiple PCs or other devices. The function needs a data connection to a mobile network and may result in data charges.

#### **TIPS:**

- ◆ The PC accesses the Internet via the device’s mobile network. Make sure to set up the GPRS/EDGE/3G connection correctly before you try to use the device as a Wi-Fi hotspot.

- ◆ When the portable Wi-Fi hotspot function is enabled, you cannot access the Internet with any application on your device via its Wi-Fi connection.

### ***Enabling the Wi-Fi Hotspot***

1. Tap **Home > Menu > Settings > Wireless & networks > Tethering & portable hotspot** and tick the **Portable Wi-Fi hotspot** check box.
2. Tap **Portable Wi-Fi hotspot settings > Configure Wi-Fi hotspot**.
3. Change the name of the hotspot and its security settings, if necessary. The default hotspot is an open one. You can tap **Open** and choose **WPA2 PSK** to set up a password. The password must have at least 8 characters.
4. Tap **Save**. Now you can find the hotspot on other devices and connect to it.

### ***Disabling the Wi-Fi Hotspot***

Tap **Home > Menu > Settings > Wireless & networks > Tethering & portable hotspot** and clear the **Portable Wi-Fi hotspot** check box.

### ***Browsing the Internet***

You can use your device to connect to the Internet via a GPRS, EDGE, 3G, or Wi-Fi connection.

Tap **Home >  > Browser**.

**There are different ways to open web pages:**

Tap the address bar to enter the website you want to browse. Then tap **Go**.

Tap  beside the address bar or tap **Menu > Bookmarks**. Select the bookmarked webpage you want to open.

Tap  beside the address bar or tap **Menu > Bookmarks**. Choose an item from the **Most visited** tab or **History** tab.

### ***Browsing Options***

Press **Menu** to access the following options when browsing web pages.

- ◆ Open a **New window** for web browsing.
- ◆ Access **Bookmarks**, most visited web sites, and browsing history.
- ◆ Switch browsing **Windows**.
- ◆ **Refresh** the current web page.
- ◆ Tap **More** to forward to the next web page, add bookmarks, search for text, select text, share page URL, check page info or download history, or configure browser settings.

Tap and hold a URL link in a web page to open, bookmark, save, share the link, or to copy the link URL.




### ***Using Bookmarks***


To bookmark a web page, open it and tap  or **Menu > Bookmarks**. Then tap **Add** or **Add bookmark**. Give the bookmark a name and tap **OK**.

**TIPS:** You can press **Menu > List view/Thumbnail view** to change how you view bookmarks on your device screen.

### ***Editing a Bookmark***

1. Open a Browser window.
2. Tap  or **Menu > Bookmarks**.
3. Select an item you want to edit and press it until the shortcut menu pops up.
4. Select **Edit bookmark**.
5. Edit the name or location, and then tap **OK** to save.

### ***Deleting a Bookmark***

1. Open a Browser window.
2. Tap  or **Menu > Bookmarks**.
3. Select an item you want to delete and press it until the shortcut menu pops up.
4. Select **Delete bookmark** and tap **OK** to confirm.

### ***Changing Browser Settings***

Tap **Menu > More > Settings** from a browser window to change browser settings.

### **Bluetooth®**

Bluetooth® is a short-range wireless communication technology. Phones or other devices with Bluetooth capabilities can exchange information wirelessly within a distance of about 10 meters. The Bluetooth devices must be paired before the communication is performed.

### ***Turning Bluetooth On/Off***

Tap **Home >  > Settings > Wireless & networks** and select **Bluetooth**. When Bluetooth is on, the  icon appears in the status bar.

If you want to turn Bluetooth off, just clear the Bluetooth check box.

**NOTE:** If you switch off your device while Bluetooth is turned on, when you switch on the device again, Bluetooth turns on automatically.

### ***Making Your Device Visible***


In order to work with other phones or devices that have Bluetooth, you need to make your device 'visible' to them.

1. Tap **Home >  > Settings > Wireless & networks > Bluetooth settings**.

2. Select **Bluetooth** if it isn't already selected.
3. Select **Discoverable** to make your device visible for 120 seconds. To make your device 'invisible', simply clear the **Discoverable** check box.


### ***Changing the Device Name***

When your device is visible to other Bluetooth devices it listed by its name, and you can choose – for example: 'Ben's Phone'.

1. Tap **Home** >  > **Settings** > **Wireless & networks** > **Bluetooth settings**.
2. Select **Bluetooth** if it is not already selected.
3. Tap **Device name**.
4. Edit the name and tap **OK**.

### ***Pairing With Another Bluetooth Device***

To pair with another Bluetooth device, you need to turn the Bluetooth function on, for both devices and make the other Bluetooth device visible.

1. Tap **Home** >  > **Settings** > **Wireless & networks** > **Bluetooth settings**.
2. Tap **Scan for devices**. Your device will show all visible Bluetooth devices (in range) in its **Bluetooth devices** list.
3. Select the device you want to pair with.



4. If required, enter your PIN and tap **OK**.

If a PIN is required, the same PIN should be entered on the other device.


## Making the Most of Multimedia



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### Taking Pictures with Your Camera



Your device has a 5-megapixel camera. Open it by tapping **Home** >  > **Camera**. Tap  to take a picture. To view it, just tap the picture in the right corner of the screen. Or select **Menu** > **Gallery** to view your pictures.

### Adjusting Camera Settings



From the Camera Screen tap  to set up focus mode, exposure, picture size/quality, color effect, ISO, anti-banding, saturation, contrast, sharpness, and to restore camera settings.

Tap  or  to choose whether to save the photo's geographic location.




Tap  to change the white balance.

Tap  or  to turn on or off flash.


Tap **1x** to zoom in or out.


**TIPS:** To change quickly from camera to camcorder or vice versa, use the switch  icon. Use the  bar to adjust the brightness.


### ***Shooting Video with Your Camcorder***

Open the camcorder by tapping **Home** >  > **Camcorder**. Then tap  to start shooting, and tap  to stop. Select the picture in the right corner of the screen to view the video you've just shot. Or tap **Menu** > **Gallery** to see all your video clips.

### ***Adjusting Camcorder Settings***


From the Camcorder Screen, tap  to adjust color effect, video quality, video/audio encoder, video duration, and restore camera settings.

Tap  to change the white balance setting.


Tap  to change video quality, video/audio encoder, and video duration together, including **High**, **Low**, **MMS**, **YouTube**, and **custom** mode.


### ***Listening to Your FM Radio***

With the FM Radio, you can search for radio channels, listen to them, and save them on your device. Note that the quality of the radio broadcast depends on the coverage of the radio stations in your area. The wired headset that comes with your device works as an antenna, so always connect the headset when using the radio. When you receive an incoming call while listening to the radio, the radio will be turned off.

- ◆ To tune in, plug your headset into your device. Tap **Home** >  > **FM Radio**.




The  icon pops up in the status bar.  
Tap Menu > Sleep to set the FM radio settings.

- ◆ Tap  to switch off the radio.

### ***Playing Your Music***

You can play digital audio files from your device's memory card.

1. Tap **Home** >  > **Music** to open the Music Screen.
2. Select **Artists/Albums/Songs/Playlists** to find the songs you want to play.
3. Tap an item from the list to start playing it.
4. Adjust the volume with **Volumes**.

### ***Creating Playlists***

Playlists help you organize your music files:

1. Select a music file that you want to add to a new playlist.
2. Tap and hold the file until a shortcut menu pops up.
3. Tap **Add to playlist**.
4. Tap **New**.
5. Type the playlist name and tap **Save**.

### ***Managing Playlists***

1. From the *Music* Screen tap **Playlists** to see them all.
2. Hold the playlist you want to play or edit until a shortcut menu pops up.
3. Tap **Play, Delete or Rename**.


### **Adding a Song to a Playlist**

1. Open **Music** and find the song under **Artists, Albums, Songs, or Playlists**.
2. Hold the song until a shortcut menu pops up.
3. Select **Add to playlist**.
4. Select a playlist.

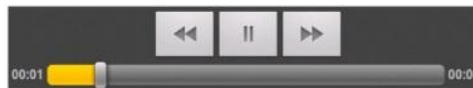
### **Configuring a Song as a Ringtone**

1. Find the music file under **Artists, Albums, Songs, or Playlists**.
2. Hold the song until a shortcut menu pops up.
3. Select **Use as phone ringtone**.


### ***Playing Your Videos***

To play a video file, tap **Home** >  > **Videos**. This opens the Videos Screen and shows the video files saved to your memory card.

Tap a video file to start playing it. Tap on the screen and the control bar appears as seen below. You can play, pause, fast forward, rewind, etc.







### ***Opening Your Gallery***

Tap **Home** >  > **Gallery**. You can use the **Gallery** to view pictures and play videos. You can also do some basic picture editing – such as setting them as wallpaper or contact icons, and sharing with friends.

### ***Making Voice Memos***

The *Sound Recorder* enables you to record voice memos. You need a microSD card to use it.

1. Tap **Home** >  > **Sound Recorder**.
2. Tap  to start recording.
3. Tap  to stop recording.
4. Tap  to play back the voice recording.
5. Tap OK to save the voice recording, or tap Discard to delete the recording.

**TIPS:** To find your recordings press **Home**>  > **Music** > **Playlists** > **My recordings**.



## Sorting out Your Phone Settings

### ***Setting Date and Time***

1. Tap **Home > Menu > Settings > Date & time**.
2. Clear the **Automatic** check box if you want to set the time and date by yourself.
3. Configure the **date**, **time**, **time zone**, and **date/time format**.

### ***Display Settings***

Tap **Home > Menu > Settings > Display**, to adjust the display settings:

- ◆ **Brightness:** Adjust the screen brightness.
- ◆ **Auto-rotate screen:** Rotate the screen display as you rotate the device.
- ◆ **Animation:** Choose the window animation.
- ◆ **Screen timeout:** Set the delay for the screen to automatically turn off.

### ***Sound Settings***

Tap **Home > Menu > Settings > Sound**, to configure the sound settings, such as ringtones and alerts.

- ◆ **Silent mode:** Select to mute all sounds except media and alarms.


- ◆ **Silence Ringer When Face Down:** Enable this function, to mute the incoming call ringtone by flipping the device over.
- ◆ **Vibrate:** Enable vibration.
- ◆ **Volume:** Tap to adjust volume levels for ringtone, media, alarm, and notification.
- ◆ **Phone ringtone:** Select the default ringtone for incoming calls.
- ◆ **Notification ringtone:** Select the default ringtone for notifications.
- ◆ **Audible touch tones:** Select to play tones when you tap the dial pad.
- ◆ **Audible selection:** Select to play a sound when you touch the screen as you make a selection.
- ◆ **Screen lock sounds:** Select to play a sound when you lock or unlock the screen.
- ◆ **Haptic feedback:** Select to enable the device to vibrate when you press soft keys or on certain user interface interactions.

To quickly switch to silent mode, hold **Volume** (down) or, if the screen is locked, drag  to the left.



### ***Language Settings***

You can change the language of your device system in two simple steps.

1. Tap **Home** >  > **Settings** > **Language & keyboard** > **Select language**.
2. Select a language from the list.

### ***Mobile Network Services***

Tap **Home** >  > **Settings** > **Wireless & networks** > **Mobile networks** to enable or disable a data service, allow data services when roaming, or set access point names for data access.

### ***Data Services When Roaming***

1. Tap **Home** > **Menu** > **Settings** > **Wireless & networks** > **Mobile networks**.
2. Tick the **Data roaming** box.

**IMPORTANT:** Data roaming may incur significant roaming charges.

### ***Disabling Data Services***

1. Tap **Home** > **Menu** > **Settings** > **Wireless & networks** > **Mobile networks**.
2. Clear the **Data enabled** check box.

### ***Switching Networks***

1. Tap **Home** > **Menu** > **Settings** > **Wireless & networks** > **Mobile Networks** > **Network Settings** > **Network operators**.

2. Tap **Search networks** to scan for available networks, tap a network to register manually.
3. Tap **Select automatically** to select preferred network automatically.

### ***Setting Access Point Names***

To connect to the Internet you can use the default Access Point Names (APN). And if you want to add a new APN, please contact the service provider to find out more instructions.


1. Tap **Home > Menu > Settings > Wireless & networks > Mobile networks > Network Settings > Access Point Names**.
2. Tap **Menu > New APN**.
3. Set the necessary parameters.
4. Tap **Menu > Save**.

### **Security Settings**

Here's how to protect your device and SIM card from unauthorized use.

### ***Protecting Your Device With a Screen Unlock Pattern***

#### **Creating Your Screen Unlock Pattern**

1. Tap **Home >  > Settings > Location & security > Set up screen lock > Pattern**.
2. Read the instructions and tap **Next**.
3. Watch the example pattern and tap **Next**.

4. Draw your own pattern and tap **Continue**.
5. Draw the pattern again and tap **Confirm**.
6. Press **Power** to lock the screen.

**TIPS:** Clear the **Use visible pattern** check box if you want to hide the pattern as you draw it on the screen.

### **Unlocking the Screen with Your Pattern**


1. Press **Power** to wake up the screen.
2. Draw the pattern you set for unlocking the screen. If you make a mistake, your device will ask you to try again.

### **Cannot recall your screen unlock pattern?**

You have up to five attempts to unlock your device. If you still cannot recall the screen unlock pattern, you can tap **Forgotten pattern?** and enter your account user name and password to reset the screen-unlock pattern.


## **Protecting Your Device with a PIN or Password**

### ***Creating a PIN or Password***

1. Tap **Home** >  > **Settings** > **Location & security** > **Set up screen lock**.
2. Tap **PIN** or **Password**.
3. Enter the numeric PIN or any password you like, and tap **Continue**.


4. Enter it again and tap **OK** to confirm.

### ***Unlocking the Screen with Your PIN or Password***

1. Press **Power** to wake up the device.
2. Drag the  icon to the right.
3. Enter the PIN or password you set.
4. Tap **OK**.

### ***Disabling Screen Lock Settings***

If you have created an unlock-pattern, PIN or password, you can disable it.

1. Tap **Home** >  > **Settings** > **Location & security** > **Change screen lock**.
2. Draw the screen-unlock pattern or enter your PIN/ password.
3. Tap **None**.

### ***Protecting Your SIM Card with a PIN***


Every SIM card comes with a PIN. The initial PIN is provided by your mobile phone carrier. It's best to lock your SIM card as soon as you can.

1. Tap **Home** >  > **Settings** > **Location & security** > **Set up SIM card lock**.
2. Select **Lock SIM card**.

3. Enter the PIN you've been given and tap **OK**.

### ***Changing Your SIM PIN***

You can change the PIN you've been given to one easier for you to remember and harder for others to guess.

1. Tap **Home** >  > **Settings** > **Location & security** > **Set up SIM card lock**.
2. Make sure that **Lock SIM card** is enabled.
3. Tap **Change SIM PIN**.
4. Enter the old PIN and tap **OK**.
5. Enter your new PIN and tap **OK**.
6. Enter the new PIN again and tap **OK**.


### ***Restoring a Locked SIM Card***

Put all your confidential passwords in a safe place for future use. If you enter the wrong SIM PIN more times than allowed, your SIM card will be locked and you cannot access the mobile phone network. Contact your operator for a PIN Unlock Key (PUK) to restore the SIM card.

### ***Setting Up Credential Storage***


This lets you select applications to access secure certificates and other credentials.

Enabling Secure Credentials

1. Tap **Home** >  > **Settings** > **Location & security**.
2. Tap **Set password** and create a password for the credential storage.
3. Select **Use secure credentials**.

**TIPS:** You can also install encrypted certificates from your microSD card by tapping **Install from SD card**.

#### ***Deleting Secure Credentials***

1. Tap **Home** >  > **Settings** > **Location & security**.
2. Tap **Clear storage** to clear credentials.



## Managing Your Device Memory

---

Tap **Home** >  > **Settings** > **Storage**.

You can view the microSD card and the device storage details.

- ◆ **Unmount/Mount SD card:** You can unmount the microSD card to safely remove it, or mount the card.
- ◆ **Erase SD card:** Erase all data on the microSD card.

**NOTE:** The SD card is not accessible while connected with a USB cable to a PC.

## Privacy: Reset to Factory Settings

Tap **Home** >  > **Settings** > **Privacy** > **Factory data reset** > **Reset phone** > **Erase everything**.

**WARNING:** All your personal information and applications that you have downloaded to your device will be erased.

## Managing Applications

---


### Managing Other Settings

#### ***Search Settings***

You can manage search settings and search history by opening *Search* and tapping **Menu > Search settings**.

- ◆ **Searchable items:** Choose what to search on the device.
- ◆ **Clear shortcuts:** Clear shortcuts to recently chosen search suggestions.

#### ***Voice Input and Output***

You can set the text-to-speech and voice recognition options by tapping **Home >  > Settings > Voice Input and Output**.

### Other Applications

---

#### **Calculator**

Tap **Home >  > Calculator**.

**TIPS:** Tap **Menu > Advanced panel** to use the scientific calculator.

#### **SIM Tool Kit**

The **SIM Tool Kit** appears on the screen only if your SIM card provides this function. To use SIM services, first insert your SIM card into the device.

Tap **Home >  > SIM Tool Kit**.

## ***LifeWatch V Health and Medical Functions***

### **Getting Started with the *LifeWatch V* Medical and Wellness Applications**

---

Press the *LifeWatch V* icon on the desktop. This activates the application and opens the license agreement.



### **License Agreement**

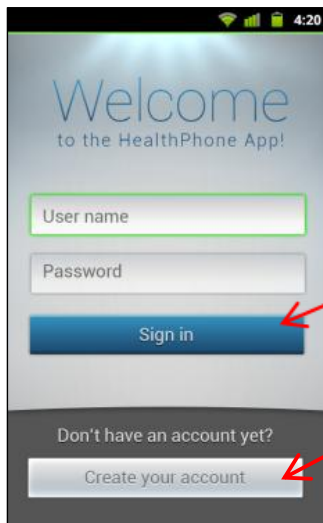
---

Please read the license agreement. The login screen appears after accepting the terms.

## First Time Launch

---

The first time you open the application the registration screens are displayed.



For registered user - enter your user name and password and tap on the **"Sign In"** button.

For new user - tap on **"Create Account"** in order to start the registration process.

### Quick access code

Create your Quick access code by selecting four numbers.

### Quick access code confirmation

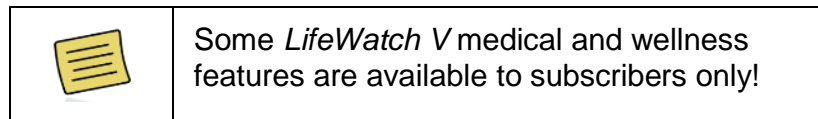
Re-enter your selected quick access code.

## Login Screen

---

This is the log-in screen for *LifeWatch V* medical applications. Use the keypad to enter your quick access code.

The *Start* screen appears.



## Guest Login

Select **Guest Login** to start **Guest Mode**.

The guest-login allows non-subscribed users to perform certain tests.




The tests are not saved, there is no connection to the remote server and the guest has a limited amount of tests that can be performed per month.



Guest log-in

### Start Screen

Select the required application to start.

Application	Icon
Test	
Diet	
Drug	
Calendar	
Information	



## Test Application


### Test General Description

---

The *LifeWatch V* implements the following test features in a single device to help you track and record your health/wellness:

- ◆ **ECG** - The graphical recording of your heart activity, to be used whenever you are concerned about your heart rhythm or if you experience the following symptoms of abnormal heart rhythms:
  - ◆ Skipped Beats
  - ◆ Pounding Heart (Palpitations)
  - ◆ Heart Racing or Irregular Pulse
  - ◆ Lightheadedness or Faintness
  - ◆ History of Arrhythmias
- ◆ **HR** – Measures the pulse rate (minimum, maximum and average rate that your heart beats).
- ◆ **Stress Level Analyzer** – Analyze the pulse rate to determine the level of mental and physiological stress.
- ◆ **BFA (Body Fat Analyzer)** – BFA uses bioelectrical impedance to determine the body fat percentage.
- ◆ **Glucose meter** – Measures the blood glucose level.
- ◆ **Body temperature** – Measures the forehead's temperature. Use to determine the body temperature.






## Test Screens Description

	<b>Wheel</b>	Use to cycle between tests and select the relevant test
	<b>Information icon</b>	Press to open the relevant information about the selected test type
	<b>Test type</b>	Displays test type
	<b>Start button</b>	Press to start test
	<b>History button</b>	Press to display test history (3 last tests)
	<b>Reminder icon</b>	Press to display the calendar
	<b>Calendar</b>	Displays the current week's reminders with the test type icon

**Note:** a green outline to a button means it is selected.

Press a button to change the display on the *Start* screen.



Press	To display
<p>Reminder</p> 	 <p><b>NOTE:</b> Tapping  <b>New</b> opens the <i>Reminder Creation</i> window for the current type of test.</p>
<p>History</p> 	 <p><b>Note:</b> Tapping the graph opens History, see page 84.</p>

### Test Wheel Icons

Glucose testing		BFA (body fat analysis)		Temperature	
ECG (electrocardiogram)		HR (heart rate)		Stress Level Analyzer	
SP02 (blood oxygen saturation)					

### NOTE:

For tests involving the use of electrodes it is important to:

- Clean electrodes with a lint free dry cloth.
- Clean your fingers with soap and dry them.
- To receive accurate measurements it is important to set up all the parameters under **Settings** prior to conducting the tests.
- Sit comfortably so that you can be relaxed during the test

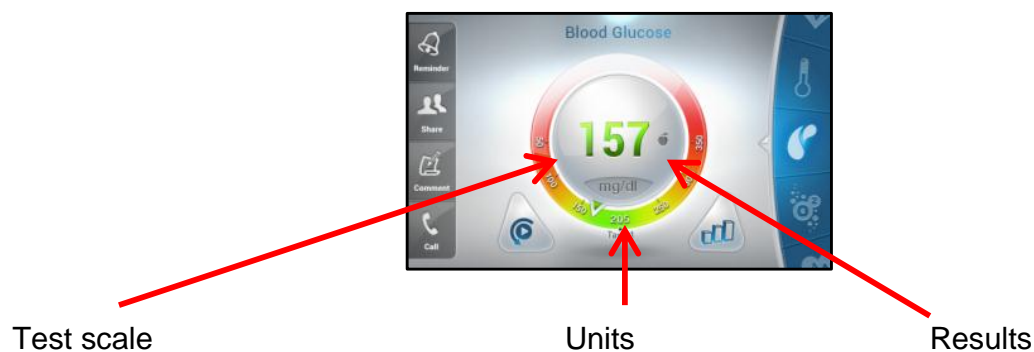


Before starting medical tests please disconnect the earphones/USB cable.

## Test Results

After a test has been performed the screen displays the results and provides extra functions.

### Example










Each test type has its own units and scale values.



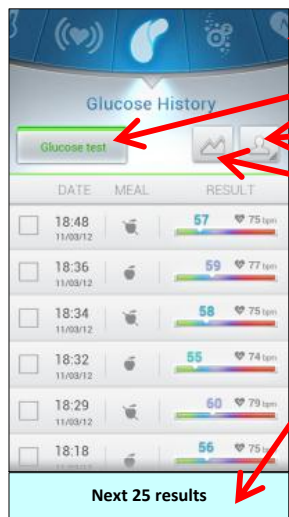
**Warning** - The user of the *LifeWatch V* should not take any actions of a medical or clinical nature based on his/her understanding or interpretation of test results without consulting a healthcare professional.

## Test Results Icons

	<b>Reminder</b> - Opens the <i>Reminder</i> window.
	<b>Share</b> - Opens the <i>Sharing Selection</i> popup, share the results via Email or SMS.
	<b>Comment</b> - Pop-up <i>Notepad</i> for commenting on results. Auto sharing results are sent without the comments.
	<b>Call</b> - Initiate a call to the Call Center (Premium Users).
	Crossed-out apple means before meal
	Apple means after meal
	Retake test
	History

## History

The screen default is to show the last test type chosen. Scroll using the wheel to change test type.



**Wheel** – scroll to change test type

**All Tests** – show all tests (all types)

**Other Users** – displays the test results of other users that you “follow”

**Graph** – display the test results graph

**Next 25 results** – displays the next 25 test results

History displays the following for each test:

<input type="checkbox"/>	Heart Rate	18:48 11/03/12	57	75 bpm
--------------------------	------------	-------------------	----	--------

Share box      Test type      Date & time      Result and threshold

Select a test to share.



Once selected a Share button is added to the end of the test list.



Share Results– select to open **Sending** (SMS/email) option.



## Performing Tests

The screen automatically goes to the last test type. Use the scroll-wheel to cycle between the various tests.

**NOTE:** see page 107 for instructions on changing the glucose measurement units.

### Blood Glucose Test

Be sure to read carefully this section, the test strip insert and the lancing device insert found in the Gluco kit before testing. Make sure you have all items needed to test:

LifeWatch V, Test Strips, Lancing Device, and Sterile Lancet

Wash and dry your hands.



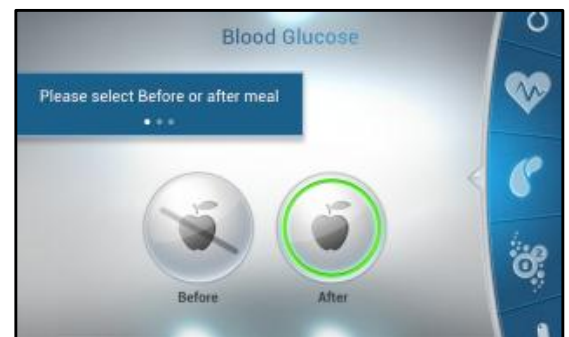
Use only the glucose strips provided with the LifeWatch V device.

1. To start the glucose test press **Start**.

The screen rotates to the horizontal mode, please hold the *LifeWatch V* horizontally.



2. A new screen opens, select **Before** or **After** meal.



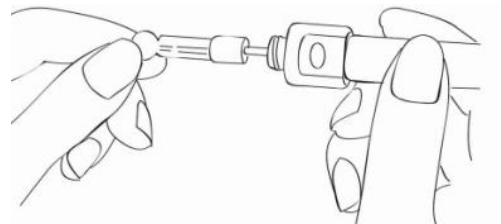
3. Please insert a new glucose strip into the glucose slot when instructed.



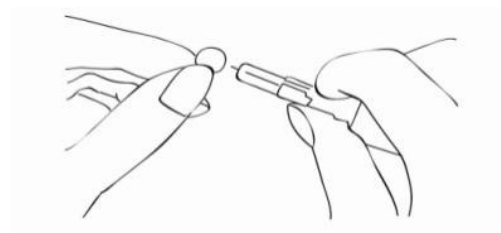


4. Prepare the lancing device:

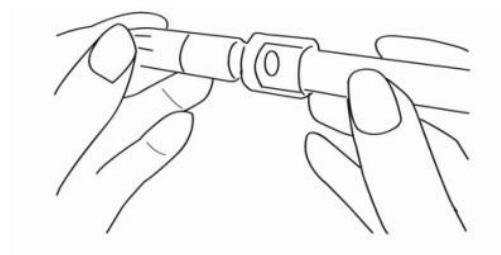
Screw off the cap of Lancing Device. Insert a lancet into the lancet holder and push down firmly until it is fully seated.



Twist the protective disk until it separates from the lancet.



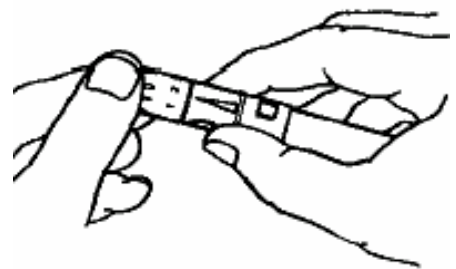
Replace the lancet device cap. Turn the cap until it is snug but not too tight.



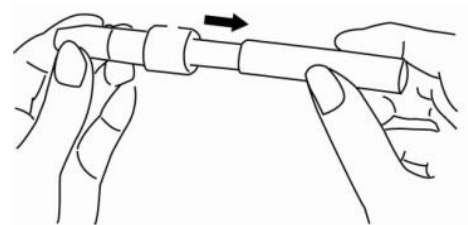
The adjustable tip offers 5 levels of skin penetration. Twist the adjustable tip in either direction until the number lines up with the Arrow:

- 1-2 for soft or thin skin,
- 3-4 for average skin,
- 5 for thick or calloused skin.

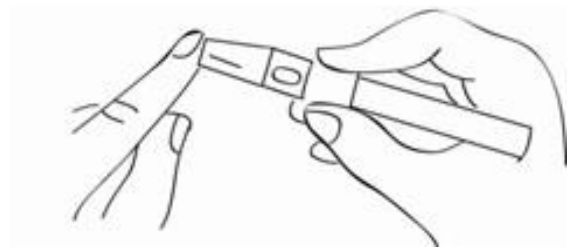
Please select the most suitable depth for you to avoid unnecessary pain.



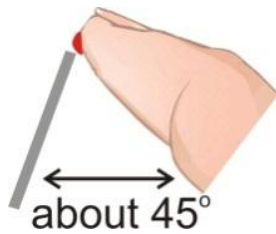
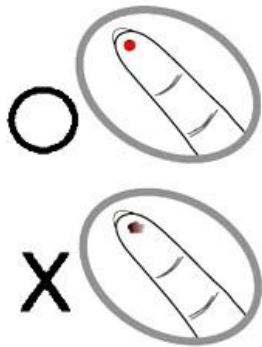
Slide the ejection/cocking control back until it clicks. If it does not click the device may have been cocked when the lancet was inserted.



5. Take a blood sample using the lancing device (see supplied lancing device instructions).




6. Place the finger with the acquired drop of blood at the tip of the glucose strip, as shown on the screen and below.



7. The *Processing* screen appears, after a few seconds the results screen appears.



8. When the test is completed the results screen appears.  
Remove the used test strip and lancet; dispose of them.

	Glucose strips are for single use only; dispose of used strips as per the instructions included with the strips.
---	--

It is now possible to:

- ◆ Retake the test by pressing the Retest button
- ◆ Use the Scroll Wheel to scroll to another test
- ◆ Display test History
- ◆ Use the options available on the left bar





### **Important Information**

Severe dehydration resulting from excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.

Test results below 70 mg/dL (3.9 mmol/L) mean low blood glucose (hypoglycemia). Test results greater than 240 mg/dL (13.3 mmol/L) mean high blood glucose (hyperglycemia). If you get results below 70 mg/dL or above 240 mg/dL, and do not have symptoms, repeat the test once. If you have symptoms or continue to get results that fall below 70 mg/dL or above 240 mg/dL, follow the treatment advice of your healthcare professional.

If you are experiencing symptoms that are not consistent with your blood glucose test results AND you have followed all the instructions described in the *LifeWatch V* User Manual, call your healthcare professional.

A red blood cell count (hematocrit) that is either very high (above 55%) or very low (below 30%) can cause false results.

### **Glucose Test Troubleshooting**

<b>Problem</b>	<b>Possible Cause(s)</b>	<b>Solution</b>
Blood glucose results are inconsistent.	<ol style="list-style-type: none"> <li>1. Not enough blood is placed on the Test Strip.</li> <li>2. Test Strips have passed their expiration date.</li> <li>3. Deteriorated Test Strip caused by heat or humidity.</li> <li>4. Device, and/or Test Strip were not at room temperature when used.</li> </ol>	<ol style="list-style-type: none"> <li>1. Rerun test with a <b>new</b> Test Strip and apply a sufficient blood to fill the Test Strip tip.</li> <li>2. Obtain new Test Strips have not yet exceeded their expiration date.</li> <li>3. Run a Control Solution Test using a <b>new</b> Test Strip. If the results are still out of range, replace the Test Strip package. See package for proper storage instructions.</li> <li>4. Allow time for the Device, Control Solution and/or Test Strips to come to room temperature before use.</li> </ol>

## Alternative Site Testing (AST)

**Important:** There are limitations for doing AST.

Please consult your healthcare professional before you do AST.

### What is AST?

Alternative site testing (AST) means that people use parts of the body other than fingertips to check their blood glucose levels.

This system provides you to test on the palm, the forearm, the upper arm, the calf, or the thigh with the equivalent results to fingertip testing.

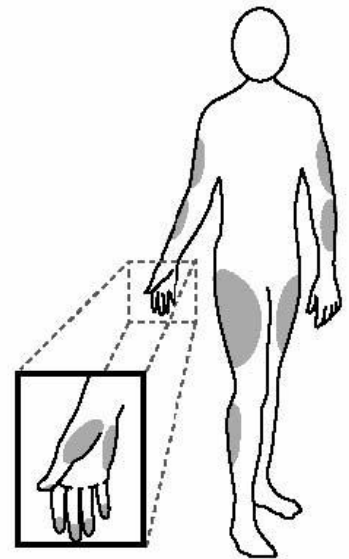
What's the advantage?

Fingertips feel pain more readily because they are full of nerve endings (receptors). At other body sites, since nerve endings were not so condensed, you will not feel as much pain as at the fingertip.

### When to use AST?

Food, medication, illness, stress and exercise can affect blood glucose levels.

Capillary blood at fingertip reflects these changes faster than capillary blood at other sites. Therefore when testing blood glucose during or immediately after meal, physical exercise, or any other event, take blood sample from your finger only.



We strongly recommend you do AST ONLY in the following intervals:

- ◆ In a pre-meal or fasting state (more than 2 hours since the last meal).
- ◆ Two hours or more after taking insulin.
- ◆ Two hours or more after exercise.

Do NOT use AST if:

- ◆ You think your blood glucose is low.
- ◆ You are unawareness of hypoglycemia.
- ◆ Your AST results do not match the way you feel.
- ◆ You are testing for hyperglycemia.
- ◆ Your routine glucose results are often fluctuating.
- ◆ You are pregnant.

### **How to increase the accuracy?**

Stimulating blood perfusion by rubbing the puncture site prior to blood extraction has a significant influence on the glucose value obtained. Blood from the site without rubbing exhibits a measurably different glucose concentration than blood from the finger. When the puncture site was rubbed (20 seconds) prior to blood extraction, the difference was significantly reduced.


## Control Solution Test

### Why Use the Control Solution?

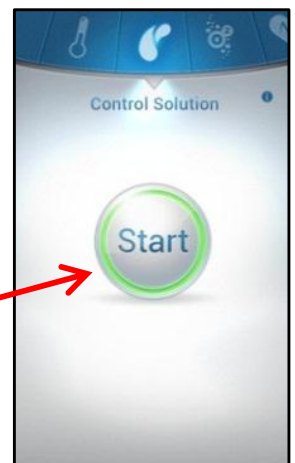
Ensure that your LifeWatch V and LifeWatch V Test Strips are working together properly. Practice testing without having to use your own blood.

#### Perform Control solution tests when:

- ◆ First receive your LifeWatch V.
- ◆ You feel your LifeWatch V or test strips are not working properly.
- ◆ You feel your test results are not accurate.
- ◆ After dropping or damaging your LifeWatch V or exposing it to liquids.
- ◆ Your healthcare professional advises you perform the test.


	Perform control solution tests for any new vial or if "abnormal" results are shown.
---	---

4. Select the Control Solution test from the options menu.
5. The following screen appears. To start the test press **Start**.
6. The screen rotates to the horizontal mode, please hold the LifeWatch V horizontally.





7. Insert the new glucose strip into the glucose slot when instructed.

	Glucose strips are for single use only; dispose of used strips as per the instructions included with the strips.
---	--



8. Place the Control Solution:
- ◆ Shake the control solution vial.
  - ◆ Place the first drop of control solution in a disposable container.
  - ◆ Clean the bottle tip using a tissue or paper towel.
  - ◆ Place a second drop at the tip of your finger



9. Using your finger place the drop of control solution on the strip in the LifeWatch V as shown. The drop is drawn into the test strip. Move your finger away when the strip window is filled



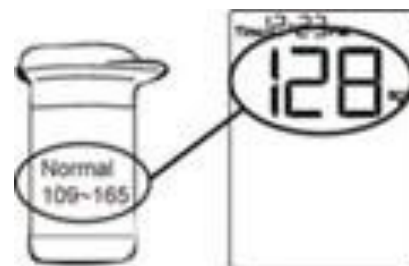
10. The *Processing* screen appears, after a few seconds the results screen appears.



11. When the test is completed the results screen appears.
12. Remove the used test strip and dispose of it.
13. Compare the result of your control solution test to the range printed on your LifeWatch V Blood Glucose Test Strip vial label for the control solution level that you used.

Your control solution result should fall within this range.

If your control solution test results are out of the range, repeat the test and refer to *Control Solution Troubleshooting* of this guide to see potential causes of error.



### Control Solution Troubleshooting

Problem	Possible Cause(s)	Solution
Control solution test results are inconsistent, or control solution test results are not within the specified range.	<ol style="list-style-type: none"><li>1. Not enough control solution is placed on the Test Strip.</li><li>2. Test Strips or control solution have passed their expiration date.</li><li>3. Deteriorated Test Strip caused by heat or humidity.</li><li>4. Device, Control Solution and/or Test Strip are not at room temperature when used.</li></ol>	<ol style="list-style-type: none"><li>1. Rerun the test with a <b>new</b> Test Strip and apply sufficient control solution to fill Test Strip tip.</li><li>2. Obtain new Test Strips and/or Control Solution that have not yet exceeded their expiration date.</li><li>3. If the results are still out of range, replace the package of Test Strips. See package for proper storage instructions.</li><li>4. Allow time for the Device, Control Solution and/or Test Strips to come to room temperature before use.</li></ol>

## ECG/HR/BFA/SP02/Stress Level Analyzer Tests

**Recommended Preparations** - Wash and dry your hands.

If your fingers are too dry or are extremely cool, accurate measurements may not be possible.

Condition	Actions
Hands are dry.	Slightly moisten hands with a wet towel, then measure.
Your hands are cold	Warm your hands by immersing in warm water or staying in a warm room. Start the measurement again.

### Special Instructions for BFA Test

The following physical conditions change the water content in the body, the measured body fat percentage may differ significantly from the real number.

- ◆ Right after vigorous exercise
- ◆ Right after taking bath or sauna
- ◆ When drinking large amounts of alcohol
- ◆ When drinking a large amount of water or after a meal

### Exceptions for BFA Test

The measured body fat percentage may differ from the actual body fat percentage for people with changing amounts of water and tissue density within their bodies.

- ◆ Children of growing stage
- ◆ Elderly people and women after menopause
- ◆ Having osteoporosis (very low bone density)
- ◆ People with a fever or swelling
- ◆ Bodybuilders or professional athletes
- ◆ Patients undergoing dialysis
- ◆ Pregnant women

### Start the Test

Use the scroll wheel to cycle between the various tests.

1. To start the test press **Start**.

The screen rotates to the horizontal mode, please hold the *LifeWatch V* horizontally.

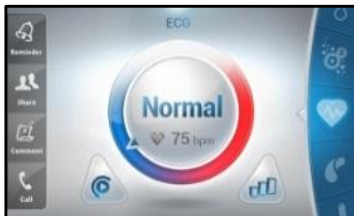
**NOTE:** The ECG test is shown as an example.

2. Follow the on-screen instructions (place fingers on the three electrodes).



3. When the test is completed the results screen appears.

ECG



SP02



Stress Level Analyzer



Heart Rate



Body Fat Percentage



It is now possible to:

- ◆ Retake the test by pressing the Retest button
- ◆ Use the Scroll Wheel to scroll to another test
- ◆ Display test History
- ◆ Use the options available on the left bar

## Body Temperature Test

Scroll to the **Thermometer** icon on the wheel.  
The following screen is displayed.

1. To start the test press **Start**.



A high fever or low body temperature requires you to seek immediate medical attention

2. The screen rotates to the horizontal mode, please hold the LifeWatch V horizontally.
3. Follow the screen instructions and place the thermometer on your forehead when instructed.





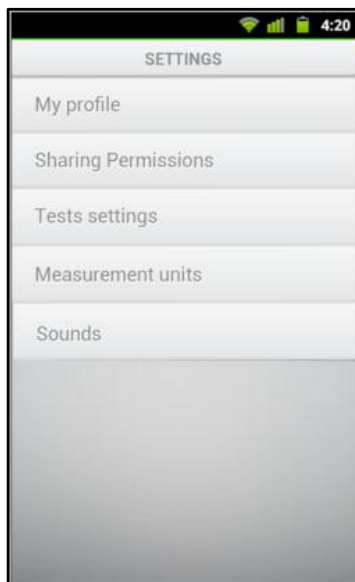
4. When the counter reaches 0 the test starts followed by beeps. Move the device from left to right, until the beeping stops (about 5 seconds).
5. The processing screen appears while you are moving the device on your forehead, the test ends when the beeping stops.
6. When the test is completed the results screen appears. It is now possible to:
  - ◆ Retake the test by pressing the Retest button
  - ◆ Use the Scroll Wheel to scroll to another test
  - ◆ Display test History
  - ◆ Use the options available on the left bar



## LifeWatchV Medical Application Settings

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The *LifeWatch V* medical application settings are divided into categories:



**My Profile**

**Sharing Permissions**

**Test Settings**

**Measurement units**

**Sounds**

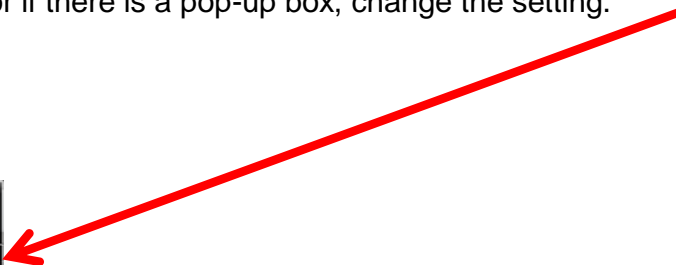
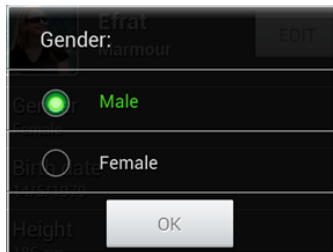
## My Profile

Press **My Profile** to open the profile details. The details that have been entered during the registration process are displayed.

To change a detail, select it by pressing it and then either enter the new details in the field or if there is a pop-up box, change the setting.

## Pop-up Example

### Gender



## Sharing Permissions

Select **Sharing Permissions** to display the list of people already assigned for sharing and to add new sharing contacts.

## Test Settings

Press on **Test Settings** to open the tests options screen. It is possible to set the desired test goal for each test.

## Measurement Units

Select to open the sub menu, tap on the measuring type you want to change.

## Sounds

Select Sounds options.



## Diet Application

### General

The Diet application assists users in staying on track and gaining their fitness goals through fitness and nutrition planners. It also includes diet and wellness support through personal nutrition and fitness management, along with personalized information.

#### Meal Planner



The *Meal Planner* is designed to track the user's caloric intake. The system is categorized into meals and the user is able to note all of the food consumed on each day. The user's calculated calorie budget appears in the right column. The user can also use the right column to track water intake, and favorite food items. The daily meals' nutritional value is displayed visually in a pie chart located at the bottom of the page. The *Meal Planner* includes a *Meal Plan Wizard*, for first time use of the *Meal Planner* section of the application.



### Exercise Tracker



*Exercise Tracker* presents the recent exercise logs, and lets the user add new logs.

Tap '**Exercise** Tracker on the scroll wheel to open this application. The screen shows the user all the previously reported exercise logs. The *Exercise Tracker* includes a pedometer that counts each step a person takes and uses it to calculate the distance the user has walked.

### Weight Tracker



*Weight Tracker* presents the recent weight logs, and lets the user add new logs.

### Water Tracker



*Water Tracker* supports the tracking and logging-in of the daily intake of water. Tap '**Water Tracker** on the scroll wheel to access the *Recent Logs* screen and to add new logs.

### Measurement Tracker



*Measurement Tracker* presents the recent body measurements logs and lets the user add new logs.

### Calendar Application

The *Calendar* application displays the set test times and medication use in a calendar format.

You can select to display only tests or only medications. The details are presented at the bottom of the screen.



### **Drug Reminder**

Using the *Drug Reminder* application to create reminders for the medications that you are taking, including usage monitoring.

The dosage, time periods, length of use and any special instructions may be added.

It is possible to check the *Reminder* details, freeze (pause) the *Reminder* or delete the *Reminder*.





## **Heart Rate Calculation Method**

### **Introduction**

This section describes the heart rate (HR) calculation within the LifeWatch V. HR is defined as the number of heart beats during a GIVEN TIME INTERVAL (usually one minute). It is reported by the algorithm each time a QRS complex is detected.

### **Method of Calculation**

The momentary HR is the inverse of the time lasting between two consecutive heart beats. As the momentary HR fluctuates due to inaccuracies in detecting the exact R wave timing eight momentary HR values are averaged to generate the displayed HR. Therefore the reported HR is the mean of the last momentary HR values WHICH CORRESPOND TO THE DETECTED R COMPLEXES FOR THE LAST 8 SECONDS.

**OCCASIONS IN WHICH THE HR IS NOT REPORTED:** If during a specific QRS complex the signal is considered as too low to be considered accurate or is considered as noise, the displayed HR will be 0.

## **Maintenance**

### **Conditions of Use**

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Your *LifeWatch V* conforms to international regulations insofar as it is used under normal conditions and in accordance with the instructions detailed in this manual.

### **Caring for your *LifeWatch V***

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- ◆ Do not open or attempt to repair your *LifeWatch V* yourself; do not tamper or attempt to remove the battery. Only authorized service personnel may repair the device.
- ◆ Do not drop your *LifeWatch V* or subject it to severe impact. Do not use extreme force when pressing the display or keys.
- ◆ Take care to dispose of the device, including the battery and electronic components, as per local/national environmental regulations.

### **Cleaning**

Clean device daily using a dry lint free cloth.

### **Disinfecting**

Disinfection is performed after each use of the *LifeWatch V* glucose meter using EPA registered germicidal disposable wipes (such as Nice-Pak Products, Inc. "Super Sani-Cloth+® Germicidal Disposable Wipe").

## Environment

- ◆ Keep the device away from extreme heat. Do not leave it on the dashboard of a car or near a heater.  
Do not leave it in any place that is extremely damp or dusty.
- ◆ As this device is not waterproof, do not use it or store it where liquids such as water, juice, coffee, etc. can splash it.
- ◆ Keep accessories that might be swallowed, away from children.
- ◆ Do not store the device under the following ambient conditions:
  - Locations exposed to direct sunlight.
  - Locations subject to high temperatures and high humidity.
  - Dusty locations.
  - Near fires or open flames.
  - Locations exposed to strong vibrations.
  - Locations exposed to strong electromagnetic fields.

### ***Preventive Maintenance***

The following simple preventive maintenance tasks should be performed weekly to ensure the continued maximum capacity performance of the device, and to reduce the possibility of failure:

- ◆ **Mechanical Inspection** - Check for splits, cracks or imperfections in the case. If you have any questions or doubts, call your service provider.

**NOTE:**

- ◆ Clean the thermometer with a dry, lint free cloth.
- ◆ Do not allow any liquid to enter the case, and avoid pouring water or other liquids on the device while cleaning.
- ◆ Never use abrasives such as wire wool or metal polish.
- ◆ During cleaning, make sure you do not expose the device to temperatures in excess of 45°C (113°F).

### Troubleshooting

Bad contact	1. Clean fingers and electrodes. 2. Gently touch electrodes.	
Inaccurate Body temperature	Make sure the thermometer lens is placed properly on your forehead while testing.	
Low/critical battery Message	Recharge the device for at least one hour.	
A medical function is not working	1. Exceeding device temperature 2. Device battery is low 3. USB cable or earphone are connected to the device	1. Device temperature is too high or low, device temperature should be 10 to 40° C. 2. Charge the device 3. Disconnect USB cable or earphone before use.
No device communication during tests	The test function has disabled the phone communication.	By the end of the test the communication will be restored.
No charging animation	Check if the adapter is properly connected; if the phone battery was completely drained it may take up to one hour until the charging animation appears.	
No history records/cannot receive ECG analysis from server	Make sure the internet connection is available and that your LifeWatch V service plan is active.	
Phone is frozen, a black screen is shown	Click on the restart button located under the device back cover.	

## Specifications

Environmental and Dimensions	
Operating temperature (C°)	Cellphone -10 to +55 Medical tests 10 to +40
Transport & storage temperature (C°)	-25 to +75
Relative humidity (%)	0 to 95, non-condensing
Atmospheric pressure range (hPa)	700 to 1060
Height (mm)	132
Width (mm)	70
Depth (mm)	13
Net Weight (gr.)	156
Main Features	
Bands	WCDMA/HSPA 850/1900/2100, GSM/GPRS/EDGE 850/900/1800/1900
Touch Lens	Yes (Capacitive Touch screen)
LCD Parameter	4.3 inch 480*800 Pixels (WVGA)
Camera	5M AF+300K FF
Processor	Qualcomm MSM7227Turbo, 800 MHz
Memory	1GB Flash + 512MB RAM

Battery Capacity (internal) LI-IO	1480mAh, 5.47 Wh, nominal voltage3.7 V, limited charge 4.2 V; battery model BAK5128800
Wi-Fi(WLAN)	IEEE 802.11b/g/n
GPS	Yes, support A-GPS also, but need network support
G-Sensor	Yes
FM Radio	Yes
Storage Card	microSD , up to 32GB
<b>Main Camera</b>	
Pixel	5M pixel
Camera technology	CMOS
White Balance	Yes
Brightness Setting	Yes
<b>Front Camera</b>	
Pixel	0.3M pixel
Camera technology	CMOS
Picture Size	Max 640*480
<b>Communication</b>	
<b>GSM</b>	
EDGE	Yes
GPRS functionality	GPRS Class 12

<b>WCDMA</b>	
HSPA	Yes (HSDPA)
USIM support	Yes
Maximum Downlink Data Rate	7.2 Mbps
USB revision	USB 2.0 high speed
USB charging	Yes
System I/O connector	Micro USB
Audio Jack	3.5 Audio jack
<b>Bluetooth</b>	
Bluetooth revision	Ver. 2.1 with BT/WiFi coexistence
Bluetooth power class	Class 2
<b>USIM</b>	
USIM support	Yes
USIM card slot USIM	One
<b>Software OS</b>	
Software OS	Android 2.3
<b>Language options</b>	
Default language pack	English
<b>Certification</b>	
Certification	CE marking (pending)



<b>Medical Module</b>	
<b>ECG</b>	
ECG sample rate transmission	250 samples /sec
Sample resolution	12 bits
<b>Heart Rate</b>	
HR measurement range	40 to 240 bpm
HR accuracy	± 5 bpm or 10% whichever is greater
R-R interval measured range	225 to 2000 msec
R-R interval measured resolution	± 2 msec
R-R interval accuracy –	4 msec
QRS detection sensitivity	> 98 %
QRS detection predictability	> 98 %
<b>Stress Level Analyzer</b>	
Number of R-R intervals which have to be measured is variable	≥40
<b>SPO2</b>	
Oxygen saturation range:	70 to 100 %
Pulse rate range:	18 to 300 pulses per minute
Measurement wavelengths:	Red 660 nanometers Infrared 910 nanometers
Accuracy SPO2	Standard deviation ± 1 digits Maximal Error ± 2 digits

Accuracy Pulse rate	3 % ± 1 digits
<b>BFA</b>	
Body fat accuracy percentage	15 % relative the Caliper measurement
<b>IR thermometer</b>	
Body temperature range	34 to 41 C°
Ambient temperature	10 to 40 C°
Measurement accuracy (vs. black body)	± 0.2 C°
<b>Glucometer</b>	
Sample Size	0.7 µL
Reaction Time	7 seconds
Hematocrit Range	20-60% (35-55)
Blood Detect	No Blood Detect
AST - Alternative Site Testing	Yes AST
Applicable Sample Type	Capillary
Code Type	Auto coding
Precision	±5%
Accuracy	±15mg/dL if ≤75mg/dl; ±20% if >75mg/dL
Measuring Range	20 ~ 600mg/dL (1.1 ~ 33.3mmol/L)

### Declaration of RoHS Compliance

To minimize the environmental impacts and take more responsibilities to the earth we live on, this document shall serve as a formal declaration that the LifeWatch V manufactured by LifeWatch Technologies Ltd. complies with Directive 2011/65 /EC of the European Parliament - RoHS (Restriction of Hazardous Substances) - with respect to the following substances:

- Lead (Pb)
- Mercury (Hg)
- Cadmium (Cd)
- Hexavalent Chromium (Cr (VI))
- Polybrominated biphenyls (PBBs)
- Polybrominated diphenyl ethers (PBDEs)

### Disposal of Your Device



The LifeWatch V device is covered by the European Directive 2012/19/EC.

All electrical and electronic products should be disposed of separately from the municipal waste stream via designated collection facilities appointed by the government or the local authorities.

The correct disposal of your old appliance will help prevent potential negative consequences for the environment and human health.

## Appendix A Warnings and Precautions




### **WARNING Potential Biohazard**


Healthcare professionals or persons using the *LifeWatch V* device on multiple patients should be aware of the following and should follow the infection control procedure approved by their facility.

All products or objects which come in contact with human blood, even after cleaning, should be handled as if capable of transmitting viral diseases.

The user should follow the recommendations for prevention of blood-borne transmissible diseases in healthcare settings, as recommended for potentially infectious human blood specimens in National Committee for Clinical Laboratory Standards, Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissue: Approved Guideline. NCCLS document M29-3. This document has complete information on the area of user protection and can be used as background material for instruction.

## Warnings

<p><b>Warning</b></p> 	<ul style="list-style-type: none"> <li>• The LifeWatch V is intended to be used in conjunction with a monitoring service that reviews the recorded transmissions and provides information to the physician for his/her final diagnostic interpretation.</li> <li>• The LifeWatch V is not intended for use as an emergency medical response system and should not be used by patients at risk for serious or life-threatening cardiac arrhythmias, such as ventricular tachycardia and ventricular fibrillation.</li> <li>• The LifeWatch V is not intended for use in the diagnosis of myocardial infarction or for chest pain monitoring.</li> <li>• Due to the risk of ignition or fire, the <i>LifeWatch V</i> is not intended for use in a hyperbaric chamber, within an oxygen tent or in the presence of flammable anesthetics / medical gases.</li> <li>• To prevent fire or shock hazard, do not expose the <i>LifeWatch V</i> to moisture, liquids or condensation.</li> <li>• To prevent an allergic reaction, do not use the <i>LifeWatch V</i> or accessories if you have a known allergy to nickel, silver or other metals.</li> <li>• The <i>LifeWatch V</i> is not defibrillation-proof. Exposure to defibrillation may damage the <i>LifeWatch V</i>, or the <i>LifeWatch V</i> may interfere with the operation of the defibrillator.</li> <li>• The user of the <i>LifeWatch V</i> should not take any actions of a medical or clinical nature based on his/her understanding or interpretation of test results without consulting a healthcare professional.</li> <li>• Classifications of test results obtained for medical modules or for wellness applications into categories such as “Low”, “Normal”, “Average”, etc. are based on well-established and widely accepted clinical sources; as other classifications may exist, the test results should not constitute the sole basis for diagnosis or for deciding on the appropriate course of medical treatment or therapy.</li> <li>• If you are experiencing symptoms that are not consistent with any of your test results, you should consult your healthcare provider, doctor or other appropriate medical professional.</li> <li>• If you are taking medications you should consult your healthcare professional concerning the possible effect of the medications on the test results.</li> </ul>
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<p><b>Warning</b></p> 	<ul style="list-style-type: none"><li>• Seek immediate medical attention in the event of a high fever or low body temperature.</li></ul> <p><b>Contraindications Heart Rate/ECG Use</b></p> <ul style="list-style-type: none"><li>• Due to the possible seriousness of the abnormal heart rhythms that can be associated with the following conditions, persons with these conditions should consult their physician before using this device:</li><li>• Coronary heart disease</li><li>• Valvular heart disease</li><li>• Heart transplant</li><li>• Heart failure</li><li>• The LifeWatch V device should not be used to monitor chest pain and it cannot predict or diagnose a heart attack (myocardial infarction).</li><li>• Do not operate the LifeWatch V in combination with the following medical electronic devices as this may cause a malfunction of this device:</li><li>• Electronic life support systems such as an artificial heart/lung.</li></ul> <p><b>Contraindications Glucose Model use:</b></p> <ul style="list-style-type: none"><li>• The Blood Glucose function is not intended for the diagnosis of, or screening for, diabetes</li><li>• The Blood Glucose function should not be used by users whose vision is impaired to the extent that their sight does not enable them to operate the device, nor by neonates or infants less than one year.</li></ul>
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**Precaution**



- The *LifeWatch V* generates, uses, and can radiate radio frequency energy and, if not used in accordance with the instruction manual, may cause harmful interference to radio communications.
- The *LifeWatch V* employs cellular technology. The location of the *LifeWatch V* and the associated environment, including cellular phone coverage in the particular area, may cause transmission interruption or delay.
- Do not open or attempt to repair the device. Only authorized service personnel may repair the system components.
- To avoid damage to the system, the system and accessories should be kept away from extreme heat, including placement of the *LifeWatch V* on the dashboard of a car or near a heater.
- The system should not be subjected to severe impact or bending force. Exposure to these types of stresses can damage the system components.
- The device is not waterproof. Do not use it or store it where liquids such as water, juice, coffee can splash.

**SP02 Test**



- Poor peripheral blood circulation may reduce the arterial pulsation, making it difficult to pick up a signal.

**Examples:** hypovolaemia (state of decreased blood volume); cold; cardiac failure; arrhythmias; peripheral vascular disease; and the position of a noninvasive blood pressure cuff.

- There is no SP02 or pulse rate alarm.
- Invalid signal will generate an alarm message.
- In cases of smoke inhalation the blood absorbs COHb\* having similar wavelengths of light as oxyhaemoglobin; therefore COHb\* will lead to an overestimation of the actual oxygen saturation.

\* Carboxyhaemoglobin (COHb)

**Gluko Test**

<p><b>Precaution</b></p> 	<ul style="list-style-type: none"> <li>• Use only the supplied or recommended glucose strips.</li> <li>• Glucose strips are for single use only; dispose of used strips as per glucose strip instructions.</li> <li>• Perform control-solution tests for any new vial or if “abnormal” results are shown.</li> <li>• Disinfection is performed after each use of the LifeWatch V glucose meter using an EPA registered germicidal disposable wipes (such as Nice-Pak Products, Inc. "Super Sani-Cloth+® Germicidal Disposable Wipe").</li> </ul> <p><b>ECG/HR/BFA/Stress Level test</b></p> <ul style="list-style-type: none"> <li>• ECG analysis is through the service as per subscription.</li> <li>• Fingers which will be in contact with electrodes must be clean and free from obstructions in order to have proper contact.</li> </ul> <p><b>Thermometer</b></p> <ul style="list-style-type: none"> <li>• Clean thermometer to allow proper readings.</li> <li>• Clean the thermometer lens with a lint free dry cloth.</li> <li>• Do not use the thermometer shortly after exercising, bathing or coming indoors.</li> <li>• Do not use the thermometer on children under 1 year of age.</li> <li>• Do not rely only on the temperature reading of children if there are health concerns; in such cases parents should seek medical advice.</li> <li>• Consult your healthcare provider, doctor or other appropriate medical professional if or when using drug therapies that may raise the forehead temperature</li> </ul>
	<p><b>Note:</b> Modifications not expressly approved by the manufacturer could void the user authority to operate the equipment. THE MANUFACTURER IS NOT RESPONSIBLE FOR ANY RADIO OR TV INTERFERENCE CAUSED BY UNAUTHORIZED MODIFICATIONS TO THIS EQUIPMENT. SUCH MODIFICATIONS COULD VOID THE USER'S AUTHORITY TO OPERATE THE EQUIPMENT.</p>



## Radio Frequency (RF) Exposure (Precautions)

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### General Statement on RF Energy

Your phone contains a transmitter and a receiver. When it is ON, it receives and transmits RF energy. When you communicate with your phone, the system handling your call controls the power level at which your phone transmits.

### EMI Considerations

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

### Body Worn Operation

Important safety information regarding radio frequency radiation (RF) exposure: To ensure compliance with RF exposure guidelines the phone must be used with a minimum of 15 mm separation from the body.

Failure to observe these instructions could result in your RF exposure exceeding the relevant guideline limits.

## Limiting Exposure to Radio Frequency (RF) Fields (Precautions)

---

For individuals concerned with limiting their exposure to RF fields, the World Health Organization (WHO) provides the following advice:

Precautionary measures: Present scientific information does not indicate the need for any special precautions for the use of mobile phones. If individuals are concerned, they might choose to limit their own or their children's RF exposure by limiting

the length of calls, or using 'hands-free' devices to keep mobile phones away from the head and body when using the LifeWatch V device as a cell phone.

Further information on this subject can be obtained from the WHO home page <http://www.who.int/peh-emf> (WHO Fact sheet 193: June 2011).

**NOTE:** During medical tests the RF function is turned off.

## **Distraction**

---

### **Driving (Precautions)**

Using the device as a phone or medical device while driving (even with a hands free kit) can cause distraction and lead to an accident. You must comply with local laws and regulations restricting the use of wireless devices while driving.

### **Operating Machinery (Precautions)**

Full attention must be given to operating the machinery in order to reduce the risk of an accident.

## **Product Handling (Precautions)**

---

### **General Statement on Handling and Use**

Please switch the device off whenever the use of a phone is prohibited. Use of your phone is subject to safety measures designed to protect users and their environment.

- ◆ Always treat your device and its accessories with care and keep it in a clean and dust-free place.
- ◆ Do not expose your device or its accessories to open flames or lit tobacco products.
- ◆ Do not expose your device or its accessories to liquid, moisture or high humidity.
- ◆ Do not drop, throw or try to bend your device or its accessories.
- ◆ Do not use harsh chemicals, cleaning solvents, or aerosols to clean the device or its accessories.
- ◆ Do not paint your phone or its accessories.
- ◆ Do not attempt to disassemble your phone or its accessories, only authorized personnel can do so.
- ◆ Do not expose your device or its accessories to extreme temperatures.

- ◆ Please check local regulations for disposal of electronic products.
- ◆ Do not carry your device in your back pocket as it could break when you sit down.

#### **Children**

Do not leave your device and its accessories within the reach of small children or allow them to play with it. They can hurt themselves or others, or they can accidentally damage the device.

Your device contains small parts with sharp edges that can cause an injury or may become detached and create a choking hazard.

#### **Demagnetization**

To avoid the risk of demagnetization, do not allow electronic devices or magnetic media close to your device for a long period of time.

#### **Electrostatic Discharge (ESD)**

Do not touch the metal connectors of the SIM card.

#### **Antenna**

Do not touch the internal antenna.

#### **Normal Use Position**

When placing or receiving a phone call, hold your phone to your ear, with the bottom towards your mouth.

#### **Air Bags**

Do not place a phone in the area over an air bag or in the air bag deployment area as an airbag inflates with great force and serious injury could result.

Store the phone safely before driving your vehicle.

#### **Seizures/Blackouts**

The phone can produce a bright or flashing light. A small percentage of people may be susceptible to blackouts or seizures (even if they have never had one before) when exposed to flashing lights or light patterns such as when playing games or watching video. If you have experienced seizures or blackouts or have a family history of such occurrences, please consult a physician.

### **Repetitive Strain Injuries**

To minimize the risk of Repetitive Strain Injury (RSI) when texting or playing games with your device:

- ◆ Do not grip the device too tightly.
- ◆ Press the buttons lightly.
- ◆ Use the special features which are designed to minimize the times of pressing buttons, such as Message Templates and Predictive Text.
- ◆ Take occasional breaks to stretch and relax.

### **Emergency Calls**

This phone, like any wireless phone, operates using radio signals, which cannot guarantee connection under all conditions; therefore, you must never rely solely on any wireless phone for emergency communications.

### **Loud Noise**

This phone is capable of producing loud noises, which may damage your hearing. Turn down the volume before using headphones, Bluetooth stereo headsets or other audio devices.

### **Phone Heating**

Your phone may become warm during charging and during normal use.

## **Electrical Safety (Precautions)**

---

### **Accessories**

Use only approved accessories. Do not connect with incompatible products or accessories. Take care not to touch or allow metal objects, such as coins or key rings, to contact or short-circuit in the battery terminals.

### **Connection to a Car**

Seek professional advice when connecting a phone interface to the vehicle electrical system.

### **Faulty and Damaged Products**

Do not attempt to disassemble the phone or its accessories.

Only qualified personnel are allowed to service or repair the device or its accessories. If your device or its accessories were submerged in water, punctured, or subjected to a severe fall, then do not use the device or its accessories until they have been checked at an authorized service center.

#### **General Statement on Interference**

The precautions listed below must be taken when using the phone in close proximity to personal medical devices, such as pacemakers and hearing aids.

#### **Pacemakers**

Pacemaker manufacturers recommend that a minimum separation of 15 cm be maintained between a mobile phone and a pacemaker to avoid potential interference with the pacemaker. To achieve this, use the phone on the opposite ear to your pacemaker and do not carry it in a breast pocket.

#### **Hearing Aids**

People with hearing aids or other cochlear implants may experience interfering noises when using wireless devices or when one is nearby.

The level of interference will depend on the type of hearing device and the distance from the source of interference, increasing the separation between them may reduce the interference. You may also consult your hearing aid manufacturer to discuss alternatives.

#### **Use of LifeWatch V with other Medical Devices**

Please consult your doctor and the device manufacturer to determine if operation of your phone may interfere with the operation of your medical device.

#### **Hospitals**

Switch off your wireless device when requested to do so in hospitals, clinics or health care facilities. These requests are designed to prevent possible interference with sensitive medical equipment.

#### **Aircraft**

Switch off your wireless device whenever you are instructed to do so by airport or airline staff. Consult the airline staff about the use of wireless devices on board the aircraft. If your device offers a 'flight mode', this must be enabled prior to boarding an aircraft.

### **Interference in Cars**

Please note that because of possible interference to electronic equipment, some vehicle manufacturers forbid the use of mobile phones in their vehicles unless a hands-free kit with an external antenna is included in the installation.

## **Explosive Environments (Precautions)**

---

### **Petrol Stations and Explosive Atmospheres**

In locations with potentially explosive atmospheres, obey all posted signs instructing to turn off wireless devices such as your phone or other radio equipment.

Areas with potentially explosive atmospheres include fuelling areas, below decks on boats, fuel or chemical transfer or storage facilities, areas where the air contains chemicals or particles, such as grain, dust, or metal powders.

### **Blasting Caps and Areas**

Power off your mobile phone when in a blasting area or in areas posted power off “two-way radios” or “electronic devices” to avoid interfering with blasting operations.

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UG-00079 rev04 11/12

# **EXHIBIT 3**



# User's Manual

**Non-Invasive Cardiac Output Monitor  
Model 7300**

February 1, 2001

Catalog No. 9226-23-05





## *Thank you ...*

---

Thank you for purchasing the NICO® Non-Invasive Cardiac Output monitor from Novametrix.

NICO® measures cardiac output through respiratory gas analysis based on the well accepted Fick Principle, providing continuous and accurate display of cardiac output. The monitor also operates in Respiratory Mechanics-only mode, providing the clinician with a respiratory profile of the patient through a combination of capnography, airway flow and pressure, and pulse oximetry.

We expect that you will find the application and use of NICO® extremely simple, making it easy to adopt this exciting technology into your clinical practice. NICO® can provide accurate cardiac output values without the need for invasive procedures, benefitting the patient, the clinician, and the health care system in general.

We appreciate your patronage and look forward to developing a long-term relationship with you and your institution.

Sincerely,



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## Introduction

---

### *About this manual*

This manual is written for clinical personnel using the Novamatrix NICO® Non-Invasive Cardiac Output Monitor, Model 7300, and the sensors and accessories intended for use with the monitor.

This document contains information which is proprietary and the property of Novamatrix Medical Systems Inc., and may not be reproduced, stored in a retrieval system, translated, transcribed, or transmitted, in any form, or by any means, without the prior explicit written permission of Novamatrix Medical Systems Inc. Novamatrix reserves the right to change specifications without notice.

### *NICO® Monitor Technical Description*

Per requirements of IEC 601-1, the NICO® monitor is classified as class II equipment, internally powered, with type BF applied part, and an enclosure protection rating of IPX0. The NICO® monitor is Year 2000 compliant.

Transport/Storage: -10 to +55° C (14-131° F), 10-95% R.H. non-condensing  
Operating Conditions: 10 to +40° C (50 to 104° F), 10-90% R.H. non-condensing

The NICO® monitor, Model 7300, contains no user serviceable parts. Refer servicing to qualified service personnel. A technical Service Manual is available for use by technical personnel.

### *Manufacturing Quality & Safety*

The Novamatrix Medical Systems Inc. manufacturing facility is certified to both ISO 9001 and EN46001 (MDD93/42/EEC Annex II). Novamatrix' products bear the "CE 0086" mark. The product is certified by Underwriter's Laboratories (UL) to bear the UL mark; and tested by TÜV Rheinland to IEC 601-1/EN60601-1.

### *Declaration of Conformity with European Union Directive*

The Authorized Representative for Novamatrix equipment is:

D.R.M. Green  
European Compliance Services Limited,  
Oakdene House,  
Oak Road,  
Watchfield  
Swindon, Wilts SN6 8TD  
United Kingdom

### *Trademarks and Patents*

CAPNOSTAT CO<sub>2</sub> Sensor and NICO are registered trademarks (®); NICO<sub>2</sub> and the stylized NICO<sub>2</sub> with CO<sub>2</sub> shadow, NICO Sensor, NICO Loop and CObar (cardiac output confidence bar), SuperBright and Y-Sensor are trademarks (™) of Novamatrix Medical Systems Inc. Other trademarks and registered trademarks are the property of their respective owners.

NICO® and its sensors and accessories are covered by the following USA patents: 4,859,858, 4,859,859, 4,914,720, 5,146,092, 5,153,436, 5,190,058, 5,206,511, 5,251,121, 5,347,843, 5,369,277, 5,379,650, 5,398,680, 5,535,633, 5,616,923, 5,693,944, 5,789,660, 5,793,044, 5,820,550, 5,891,026, 5,999,834, 6,098,622, 6,126,610, D424,193, 6,179,784. Other patents pending.

### *Manual Revision History*

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## Welcome to NICO®

### General Description

NICO®, a Non-Invasive Cardiac Output monitor from Novametrix Medical Systems Inc., non-invasively measures and displays cardiac output (C.O.). The NICO® monitor, Model 7300, also displays cardiac index and stroke volume, as well as various respiratory monitoring parameters including CO<sub>2</sub> elimination (VCO<sub>2</sub>) and alveolar minute ventilation. In Respiratory Mechanics mode, NICO® can be used as a respiratory profile monitor, without cardiac output displayed. In either mode, NICO® provides the clinician with important information to aid in precise and efficient patient management.

### Indications

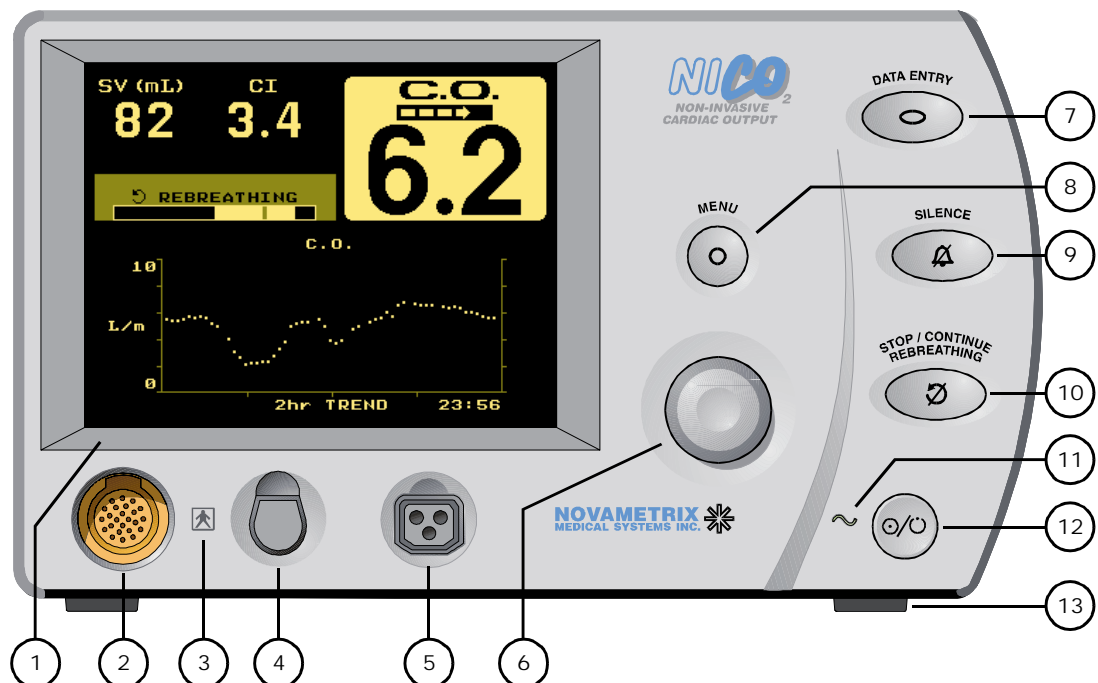
The NICO® monitor is indicated for use by technically skilled clinical personnel. In Cardiac Output mode, the monitor is used for the monitoring of cardiac output and various respiratory parameters of adult patients receiving mechanical ventilation. In Respiratory Mechanics mode, the NICO® monitor is used for monitoring the respiratory parameters of adult, pediatric and neonatal patients. NICO® is not intended for any other purpose.

### Contraindications

In Cardiac Output mode, use of the NICO® monitor is contraindicated in patients in whom a small rise (3-5 mmHg, 0.4-0.67 kPa) in their PaCO<sub>2</sub> level cannot be tolerated.

### Front Panel

The NICO® monitor's front panel includes a display screen, sensor input connectors, a control knob, and operational push button keys and indicators that are explained below.

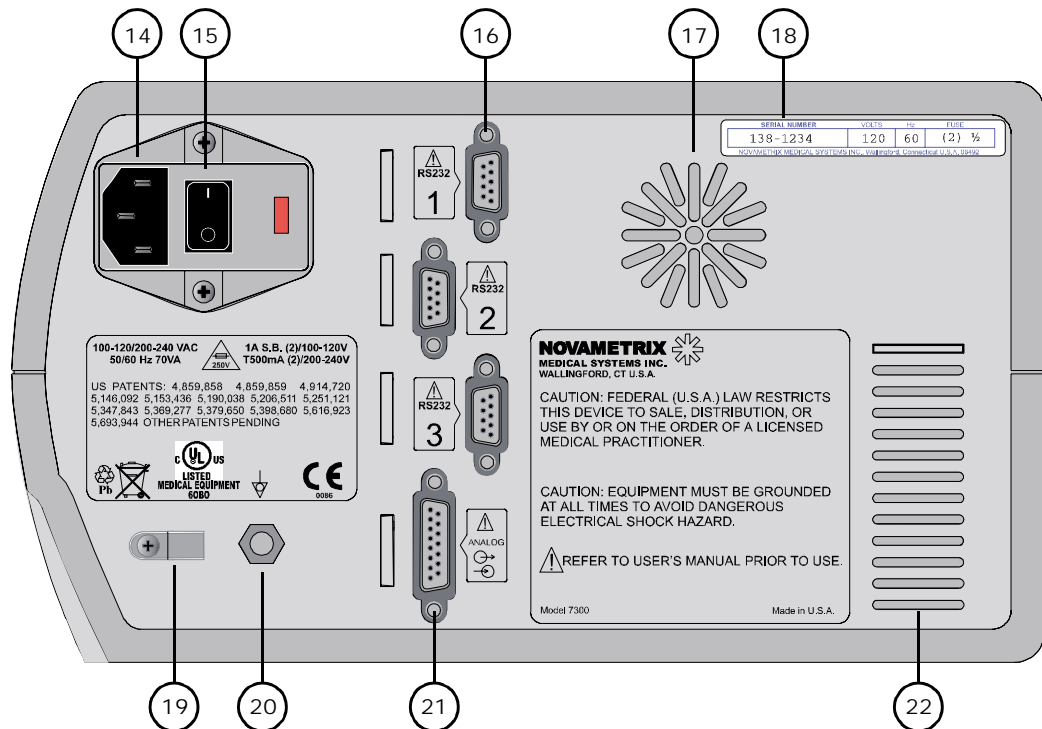


- 1 **Display Screen.** The screen displays NICO® data, respiratory mechanics, trends, waveforms and messages, along with setup and configuration data.
- 2 **CAPNOSTAT® CO<sub>2</sub> Sensor Input Connector.** Connect only a Novamatrix CAPNOSTAT® CO<sub>2</sub> Sensor, Catalog Number 9567-00 here.
- 3 **Connector Isolation Icon.** Identifies the connector to either side of this icon as a type BF patient isolation connection.
- 4 **Pulse Oximetry Sensor Input Connector.** Connect only Novamatrix pulse oximetry sensors and extension cables approved for use with the NICO® monitor.
- 5 **NICO Sensor™ Input Connector.** Connect only Novamatrix NICO Sensors™, Catalog Number 8950-00, 8951-00 and 8952-00 or Novamatrix CO<sub>2</sub>/Flow sensors, Catalog Number 9765-00, 9766-00 and 9767-00.
- 6 **KNOB.** The **KNOB** is used to select monitoring screens, scroll through menus and to change or enter values. The **KNOB** is generally turned to access different monitoring screens and to highlight menu options, and pressed to accept or change those selections.
- 7 **DATA ENTRY key.** Press to activate the **DATA ENTRY** screen and illuminate the key's green icon. Press the key again to return to the previously displayed screen. From the **DATA ENTRY** screen, you can enter patient information including height, weight and respiratory gas mixture, and access the **ABG DATA ENTRY** screen.
- 8 **MENU key.** Press to activate the **SELECT A SCREEN** menu and illuminate the key's green icon. Press the key again to return to the previously displayed screen. From the **SELECT A SCREEN** menu you can, by turning the knob, highlight the screen you wish to display. Press the **MENU** key or the **KNOB** to display that selected screen.
- 9 **SILENCE key.** The **SILENCE** key is used to mute/prevent audible alerts. It also visually indicates the presence of a "High Priority Alert". The Silence feature operates in two modes; a temporary "2 Minute Silence" mode and an "Audio Disabled" mode.
  - 2 Minute Silence — Press and release to activate or deactivate the two minute silence. The key's icon illuminates amber when active and audible alerts will be muted for two minutes, after which the icon turns off and any audible alert will sound.
  - Audio Disabled — Press and hold for one second to prevent or allow any audible alerts. The key's icon illuminates and flashes amber to indicate that all audible alerts are being suppressed.
  - High Priority Alerts — (See "NICO® Alert Priorities" on page 56) The **SILENCE** key's icon illuminates and flashes red to indicate High Priority Alert is active. The icon alternately flashes red and amber if the audio is disabled and a High Priority Alert is active.
- 10 **STOP/CONTINUE REBREATHING key.** Press to start NICO® monitoring and the automatic rebreathing process. Subsequent presses will stop (amber indicator illuminated) or continue (amber indicator off) the rebreathing process. Press and hold for two seconds to reset the NICO® algorithm; the C.O. value and averaging filter will be cleared. The **STOP/CONTINUE REBREATHING** key will be amber and inactive in Respiratory Mechanics mode.
- 11 **AC Mains Power Indicator.** This icon illuminates green to indicate AC Mains power is applied to the monitor. To illuminate the icon, the monitor must be plugged into the AC outlet and the monitor's rear panel power switch must be on ("I").
- 12 **OPERATE/STANDBY key.** Press this key to turn the monitor on. If connected to the AC outlet, the monitor uses AC power, otherwise it powers up using its internal battery (provided the battery is charged). Press the **OPERATE/STANDBY** key again to put the monitor into Standby mode (if using AC power) or to turn it off (if using battery power).
- 13 **Kickstand (front and rear).** The NICO® monitor can be positioned for better viewing from above or below by extending the kickstand at the front or rear of the monitor.

## Rear Panel

The NICO® monitor's rear panel includes an AC Mains power input module, three RS232 serial communications ports, an analog input/output port, equipotential connector, fan and ventilation slots, and the monitor's serial number label. These are explained below.

## Symbols



- 14 AC Mains Power Cord Connection.** Connect only approved hospital-grade line cords to this connector.
- 15 AC Mains Power Switch.** This switch controls the flow of AC current into the NICO® monitor. Press the “|” portion of the switch to supply the monitor with AC power, or the “O” portion of the switch to interrupt the flow of AC power. If supplied with AC power, the monitor illuminates the front panel AC Mains Power Indicator, energizes the fan and recharges the internal battery.
- 16 RS232 Communications Ports.** Three 9-pin serial communications ports provide for digital communications with the NICO® monitor. (See “RS232 Communications” ).
- 17 Fan.** The fan draws air in through the monitor. Do not block the fan’s air intake slots.
- 18 Serial Number Label.** The NICO® monitor’s serial number is shown here. Refer servicing to qualified personnel.
- 19 Power cord retaining clip.** If desired, remove the screw, slip the cord through the clip and insert and tighten the screw. Use only the supplied screw to secure the clip.
- 20 Equipotentiality.** Connection to the monitor’s chassis (earth ground system).
- 21 Analog Input/Output Port.** This 15-pin connector provides analog signal output capability for the NICO® monitor (Input reserved for future use).
- 22 Ventilation Slots.** Do not block the air ventilation slots.

## Symbols

These symbols may be found on the NICO® monitor, its sensors, accessories and documentation.



**Attention**  
Consult manual for detailed information.



**Single Patient Use**  
Treat in accordance with protocol for “single patient use” items.



**Patient Isolation**  
Identifies the patient isolation connection as type BF.



**AC Mains Power Switch**  
“|” ON-connection to mains;  
“O” OFF-disconnection from mains



**Mains Fuse Rating**  
Mains rating for replacement fuses



**Separate collection**  
Take appropriate steps to ensure that spent batteries are collected separately when disposed of. This symbol is found on the internal battery and the monitor enclosure.



**Recyclable item**  
This symbol is found on the internal battery and the monitor enclosure.



**Equipotentiality**  
Connection to monitor's chassis.



**Heavy Metal Content**  
Indicates heavy metal content, specifically lead. This symbol is found on the internal battery and the monitor enclosure.

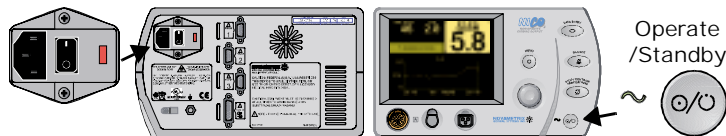
## AC/Battery Operation

The NICO® monitor is designed to be operated from AC Mains power. An internal battery provides uninterrupted monitoring and trending capability for short periods (no more than 45 minutes) if the AC power is removed.

### AC Mains Operation

To operate NICO® from AC Mains power:

- 1 Plug the line cord into the rear panel connector and the AC Mains power outlet.
- 2 Set the rear panel power switch to the On "I" position.
  - The front panel AC Mains Power indicator illuminates.
  - The monitor's fan turns on.
  - The internal battery starts to recharge.



- 3 Press the front panel **Operate/Standby** key to turn the monitor on and off.

### Battery Operation

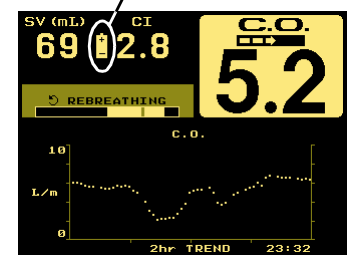
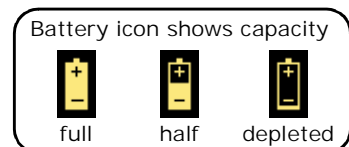
The NICO® monitor automatically switches to battery power from AC Mains power if the AC source is removed. A fully charged battery will power the monitor for up to 45 minutes. While on battery power, NICO® displays a battery icon that "drains" as power is consumed.

The battery icon starts to flash when approximately 5 minutes of battery power remain. An audible alert tone also sounds.

Reconnect to AC Mains power or the monitor will automatically shut off. A depleted battery may require 12-16 hours to fully recharge.

To operate NICO® on battery power:


- 1 Unplug the line cord or set the rear panel power switch to the Off "O" position.
  - The front panel AC Mains Power indicator turns off.
- 2 Press the front panel **Operate/Standby** key to turn the monitor on and off.



## NICO® Parameter List


**Cardiac Output mode** The NICO® monitor displays the parameters described in this table.

Label	Parameter	Range/Units	Description	Screen Display
C.O.	Cardiac Output	0.5-19.9 L/min	Volume of blood pumped by the heart each minute	All
CO-a	Average Cardiac Output	0.5-19.9 L/min	C.O. averaged value, displayed when the fast-mode cardiac output mode is chosen for large display.	Last Completed Cycle rebreathing curve & Tabular Data
CO-f	Fast-mode Cardiac Output	0.5-19.9 L/min	C.O. unaveraged value, displayed when the average cardiac output mode is chosen for large display.	Last Completed Cycle rebreathing curve & Tabular Data
Cdyn	Dynamic Compliance	0-500 ml/cmH <sub>2</sub> O	Volume the lungs expand for a given pressure  Note that if the ventilator is set for an inspiratory pause that is detected by NICO, Cdyn becomes Cstat.	Numerics & Tabular Data
CI	Cardiac Index	0-9.9 L/min/m <sup>2</sup>	C.O. divided by body surface area	All
ETCO <sub>2</sub>	End Tidal Carbon Dioxide	0-150 mmHg 0-20.0 % 0-20.0 kPa	Maximum CO <sub>2</sub> plateau value at the end of the breath (reflects alveolar CO <sub>2</sub> )	Numerics, Respiratory Numerics, CO <sub>2</sub> /SpO <sub>2</sub> , SBCO <sub>2</sub> , Tabular Data & rebreathing curves
Insp CO <sub>2</sub>	Inspired Carbon Dioxide	3-50 mmHg 0.4-6.7 % 0.4-6.7 kPa	Maximum CO <sub>2</sub> value observed during the baseline portion of the Inspiratory phase of the breath (baseline shift above zero point)	General Message Area (if above 3 mmHg for 10 sec (0.4 % or kPa))
MAP	Mean Airway Pressure	0-100 cmH <sub>2</sub> O	Mean (average) pressure in the airway throughout the breath	Numerics & Tabular Data
MV	Minute Volume	2-40 L/min Adult	Volume (in liters) of gas delivered to the patient per minute	Numerics, Respiratory Numerics & Tabular Data
MV alv	Alveolar Minute Volume	0.05-16 L/min	MV less deadspace (wasted) ventilation	Numerics, Respiratory Numerics & Tabular Data
PCBF	Pulmonary Capillary Blood Flow	0.5-19.9 L/min	Portion of the cardiac output that is effective in gas exchange	3 min Cycle in Progress rebreathing curve & Tabular Data
PeCO <sub>2</sub> /FeCO <sub>2</sub>	Mixed expired CO <sub>2</sub>	0-100 mmHg, 0-13.2 kPa or %	Volume weighted average CO <sub>2</sub> in the breath	Respiratory Numerics & Tabular Data
PEEP	Positive End Expiratory Pressure	0-99 cmH <sub>2</sub> O	Pressure in the lungs at the end of expiration	Numerics, Flow/Pressure & Tabular Data
PEF	Peak Expiratory Flow	2-180 L/min	Highest absolute flow rate during expiration	Tabular Data
PIF	Peak Inspiratory Flow	2-180 L/min	Highest absolute flow rate during inspiration	Tabular Data
PIP	Peak Inspiratory Pressure	0-120 cmH <sub>2</sub> O	Peak (highest) pressure in the airway during inspiration	Numerics, Flow/Pressure & Tabular Data

Label	Parameter	Range/Units	Description	Screen Display
	Pulse Rate	30-250 bpm	Number of pulse beats per minute	Numerics, CO <sub>2</sub> /SpO <sub>2</sub> & Tabular Data
Raw	Airway Resistance	0-100 cmH <sub>2</sub> O/L/sec	Pressure required to cause gas flow at a given rate	Numerics & Tabular Data
RR	Respiration Rate	2-120 br/min	Number of breaths per minute	Numerics, CO <sub>2</sub> /SpO <sub>2</sub> & Tabular Data
RSBI	Rapid Shallow Breathing Index	0-1000 br/min/L	Respiratory rate divided by average spontaneous tidal volume (only calculated when RR < 57)	Respiratory Numerics & Tabular Data
SpO <sub>2</sub>	Oxygen Saturation	0-100 %	Oxyhemoglobin as a percentage of total hemoglobin less dysfunctional hemoglobin	Numerics, CO <sub>2</sub> /SpO <sub>2</sub> , Tabular Data & rebreathing curves
SV	Stroke Volume	0-250 ml	Volume of blood pumped by the heart each beat	All
SVI	Stroke Volume Index	0-125 ml	Stroke volume divided by body surface area	Tabular Data
SVR	Systemic Vascular Resistance	0-5000 dynes sec/cm <sup>5</sup>	Resistance exerted by the blood vessels on blood flow and is an indicator of left ventricular afterload.	SVR Calculation & Tabular Data
SVRI	Systemic Vascular Resistance Index	0-5000 dynes sec/cm <sup>5</sup>	SVR normalized to body surface area	Tabular Data
VCO <sub>2</sub>	Carbon Dioxide Elimination	0-3000 ml/min	Volume of CO <sub>2</sub> eliminated through the breath each minute	Numerics, Respiratory Numerics, SBCO <sub>2</sub> , Tabular Data & rebreathing curves
Vd Aw	Airway deadspace	0-500 ml	Includes added mechanical deadspace proximal to the flow sensor	Respiratory Numerics, SBCO <sub>2</sub> , Tabular Data
Vd/Vt	Deadspace to tidal volume ratio	0-1.00 ml	(PaCO <sub>2</sub> -PeCO <sub>2</sub> )/PaCO <sub>2</sub>	Respiratory Numerics & ABG Data Entry
Vd alv	Alveolar deadspace	0-500 ml	Difference between physiologic and airway deadspace	Respiratory Numerics & ABG Data Entry
Vt alv	Alveolar tidal volume	0-2400 ml	Tidal volume less airway deadspace	Respiratory Numerics, SBCO <sub>2</sub> & Tabular Data
Vte	Expired Tidal Volume	200-3000 ml	Volume of gas exhaled per breath	Respiratory Numerics, Flow/Pressure & SBCO <sub>2</sub>
Vte-m	Expired Tidal Volume - mechanical	200-3000 ml	Volume of mechanically exhaled gas, per breath	Tabular Data
Vte-s	Expired Tidal Volume - spontaneous	200-3000 ml	Volume of spontaneously exhaled gas, per breath	Tabular Data
Vti	Inspired Tidal Volume	200-3000 ml	Volume of gas inhaled per breath	Respiratory Numerics, Flow/Pressure & SBCO <sub>2</sub>
Vti-m	Inspired Tidal Volume - mechanical	200-3000 ml	Volume of mechanically inhaled gas, per breath	Tabular Data
Vti-s	Inspired Tidal Volume - spontaneous	200-3000 ml	Volume of spontaneously inhaled gas, per breath	Tabular Data

**Respiratory  
Mechanics mode**

The NICO® monitor displays the parameters described in this table.

Label	Parameter	Range/Units	Description	Screen Display
Cdyn	Dynamic Compliance	0-500 ml/cmH <sub>2</sub> O	Volume the lungs expand for a given pressure	Numerics & Tabular Data
ETCO <sub>2</sub>	End Tidal Carbon Dioxide	0-150 mmHg 0-20.0 % 0-20.0 kPa	Maximum CO <sub>2</sub> plateau value at the end of the breath (reflects alveolar CO <sub>2</sub> )	All
I:E	I:E Ratio	1:9.9 or 4:1	Ratio of inspiratory time (ti) to expiratory time (te)	Flow/Pressure
MAP	Mean Airway Pressure	0-100 cmH <sub>2</sub> O	Mean (average) pressure in the airway throughout the breath	Numerics & Tabular Data
MV	Minute Volume	0.4-40 L/min adult 0.06-30 L/min pedi. 0.01-5 L/min neonatal	Volume (in liters) of gas delivered to the patient per minute	All except Flow/Pressure & Loops
MV alv	Alveolar Minute Volume	0-16 L/min adult 0-8 L/min pediatric 0-4 L/min neonatal	MV less deadspace (wasted) ventilation	Numerics & Tabular Data
NIP	Negative Inspiratory Pressure	0 to -120 cmH <sub>2</sub> O	Maximum negative pressure during inspiratory cycle	Loops
PeCO <sub>2</sub> /FeCO <sub>2</sub>	Mixed expired CO <sub>2</sub>	0-100 mmHg, 0-13.2 kPa or %	Volume weighted average CO <sub>2</sub> in the breath	Numerics, SBCO <sub>2</sub> & Tabular Data
PEEP	Positive End Expiratory Pressure	0-99 cmH <sub>2</sub> O	Pressure in the lungs at the end of expiration	Numerics, Flow/Pressure & Tabular Data
PEF	Peak Expiratory Flow	2-180 L/min adult 0.5-100 L/min pedi. 0.25-25 L/min neo.	Highest absolute flow rate during expiration	Loops & Tabular Data
PIF	Peak Inspiratory Flow	2-180 L/min adult 0.5-100 L/min pedi. 0.25-25 L/min neo.	Highest absolute flow rate during inspiration	Loops & Tabular Data
PIP	Peak Inspiratory Pressure	0-120 cmH <sub>2</sub> O	Peak (highest) pressure in the airway during inspiration	Numerics, Flow/Pressure & Tabular Data
	Pulse Rate	30-250 bpm	Number of pulse beats per minute	All
Raw	Airway Resistance	0-100 cmH <sub>2</sub> O/L/sec adult/pediatric  0-500 cmH <sub>2</sub> O/L/sec neonatal	Pressure required to cause gas flow at a given rate	Numerics & Tabular Data
RR	Respiration Rate	2-120 br/min adult 2-150 br/min pedi. 10-150 br/min neo.	Number of breaths per minute	All
RSBI	Rapid Shallow Breathing Index	0-1000 br/min/L (adult only)	Respiratory rate divided by average spontaneous tidal volume (only calculated when RR < 57)	Loops
SpO <sub>2</sub>	Oxygen Saturation	0-100 %	Oxyhemoglobin as a percentage of total hemoglobin less dysfunctional hemoglobin	All



Label	Parameter	Range/Units	Description	Screen Display
VCO <sub>2</sub>	Carbon Dioxide Elimination	1-3000 ml/min adult/pediatric  0-300 ml/min neonatal	Volume of CO <sub>2</sub> eliminated through the breath each minute	All except Flow/Pressure & Loops
Vd Aw	Airway deadspace	0-500 ml	Includes added mechanical deadspace proximal to the flow sensor	Numerics, SBCO <sub>2</sub> , Tabular Data
Vd/Vt	Deadspace to tidal volume ratio	0-1.00 ml	(PaCO <sub>2</sub> -PeCO <sub>2</sub> ) / PaCO <sub>2</sub>	Numerics, SBCO <sub>2</sub> & ABG Data Entry
Vd alv	Alveolar deadspace	0-500 ml	Difference between physiologic and airway deadspace	Numerics, SBCO <sub>2</sub> & ABG Data Entry
Vt alv	Alveolar tidal volume	0-2400 ml adult 0-1200 ml pediatric 0-160 ml neonatal	Tidal volume less airway deadspace	Numerics, SBCO <sub>2</sub> & Tabular Data
Vte	Expired Tidal Volume	200-3000 ml adult 30-400 ml pediatric 1-100 ml neonatal	Volume of gas exhaled per breath	All except Flow/Pressure & Loops
Vte-m	Expired Tidal Volume - mechanical	200-3000 ml adult 30-400 ml pediatric 1-100 ml neonatal	Volume of mechanically exhaled gas, per breath	Tabular Data
Vte-s	Expired Tidal Volume - spontaneous	200-3000 ml adult 30-400 ml pediatric 1-100 ml neonatal	Volume of spontaneously exhaled gas, per breath	Tabular Data
Vti	Inspired Tidal Volume	200-3000 ml adult 30-400 ml pediatric 1-100 ml neonatal	Volume of gas inhaled per breath	All except Flow/Pressure & Loops
Vti-m	Inspired Tidal Volume - mechanical	200-3000 ml adult 30-400 ml pediatric 1-100 ml neonatal	Volume of mechanically inhaled gas, per breath	Tabular Data
Vti-s	Inspired Tidal Volume - spontaneous	200-3000 ml adult 30-400 ml pediatric 1-100 ml neonatal	Volume of spontaneously inhaled gas, per breath	Tabular Data

## Principles of Operation

### Non-Invasive Cardiac Output (NICO)

NICO® calculates cardiac output (C.O.) non-invasively based on respiratory gas analysis, using a technique known as “differential Fick partial rebreathing.” The key to this technique is a NICO Sensor™, consisting of a rebreathing valve and a combined CO<sub>2</sub>/Flow sensor placed in the breathing circuit. The NICO Sensor™ is placed into the ventilator circuit between the patient elbow and ventilator wye. The rebreathing valve is automatically controlled by the monitor. When the valve is activated, the flow of the inspired and expired gas is diverted through a rebreathing NICO Loop.™ When the valve is deactivated, this additional rebreathing volume is bypassed and normal ventilation resumes. Every three minutes, a baseline, rebreathing and stabilization phase occurs. (See “The NICO® Cycle” on page 27.) A non-invasive cardiac output calculation is made following the end of each three minute cycle. The calculation is based on the changes induced in CO<sub>2</sub> elimination and end tidal CO<sub>2</sub> in response to the rebreathing volume. The increase in end tidal CO<sub>2</sub>, which reflects the increase in PaCO<sub>2</sub>, is usually 3-5 mmHg (0.4-0.67 kPa) and returns to baseline in less than 30 seconds.

The Fick equation using CO<sub>2</sub> as an indicator states that cardiac output is equal to CO<sub>2</sub> elimination divided by the venous-arterial difference in the CO<sub>2</sub> content:  $VCO_2 / (CvCO_2 - CaCO_2)$ . The partial rebreathing method yields a differential form of the Fick equation, eliminating the need to measure mixed venous CO<sub>2</sub> (assumed constant during the rebreathing period and therefore cancels out of the equation). This indirect Fick method is then corrected for shunt,



based on the Nunn's iso-shunt curves using  $\text{SpO}_2$  (or entered  $\text{PaO}_2$ ) and a user-entered value for  $\text{FiO}_2$  (INSP  $\text{O}_2$ ).

### Carbon Dioxide ( $\text{CO}_2$ )

NICO® uses the CAPNOSTAT®  $\text{CO}_2$  Sensor to measure  $\text{CO}_2$  by using the infrared absorption technique. The principle is based on the fact that  $\text{CO}_2$  molecules absorb infrared (IR) light energy of specific wavelengths, with the amount of energy absorbed being directly related to the  $\text{CO}_2$  concentration. When an IR beam is passed through a gas sample containing  $\text{CO}_2$ , the electronic signal from the photodetector (which measures the remaining light energy) can be obtained. This signal is then compared to the energy of the IR source and calibrated to accurately reflect  $\text{CO}_2$  concentration in the sample. To calibrate, the photodetector's response to a known concentration of  $\text{CO}_2$  is stored at the factory in the monitor's memory. A reference channel accounts for optical changes in the sensor, allowing the system to remain in calibration without user intervention.

### Flow and Pressure

Flow and pressure measurements in the NICO® monitor are made by a fixed orifice differential pressure pneumotachometer. Respirated gas flowing through the flow sensor causes a small pressure drop across the two tubes connected to the sensor. This pressure drop is transmitted through the tubing to a differential pressure transducer located inside the monitor, and is correlated to flow according to the factory stored calibration. User calibration is not required due to the ability of the plastic injection mold to repeatedly produce precision flow sensors. The pressure transducer is automatically "zeroed" to correct for changes in ambient temperature and electronics. The NICO® monitor system software compensations allow accurate flow and volume measurements in the presence of high oxygen concentrations, anesthetic gases and helium-oxygen mixtures. When compensated, gas density and viscosity effects do not cause significant errors in flow measurement.

### Carbon Dioxide Elimination ( $\text{VCO}_2$ )

Carbon dioxide elimination ( $\text{VCO}_2$ ) is a key measurement for NICO® calculations. It is calculated based on a mathematical integration of the measured flow and  $\text{CO}_2$  signals. These signals are obtained from practically the same point at the patient's airway, thereby insuring optimal accuracy. Both the flow and  $\text{CO}_2$  sensors are integral components of the NICO Sensor™.

### Oxygen Saturation ( $\text{SpO}_2$ ) & Pulse Rate

Oxygen saturation ( $\text{SpO}_2$ ) is used by the NICO® monitor to calculate the shunt correction of the NICO® calculation, and the pulse rate is used to calculate stroke volume.

$\text{SpO}_2$  is determined using sensors containing red and infrared light emitting diodes (LEDs). The light from each LED is beamed through a pulsating vascular bed such as the patient's finger or toe. The remaining light not absorbed by the tissue reaches a photodiode light receptor in the sensor. Oxygen saturated blood absorbs different amounts of light at each wavelength as compared to unsaturated blood. Therefore, the amount of light absorbed by the blood in each pulse can be used to calculate oxygen saturation.

NICO® is calibrated to display "functional" saturation. This differs from the "fractional" saturation value displayed by most co-oximeters. Functional saturation represents the amount of oxyhemoglobin as a percentage of the hemoglobin that can be oxygenated. Dysfunctional hemoglobins, (COHb and METHb) are not included in the measurement of functional saturation.

- Functional Saturation =  $\text{HbO}_2 / 100 - (\text{COHb} + \text{METHb})$ ;  $\text{HbO}_2$  is fractional hemoglobin, COHb is carboxyhemoglobin, and METHb is methemoglobin.

Pulse Rate, derived from the pulse oximetry sensor, is calculated by measuring the time interval between the peaks of the infrared light waveform. The inverse of this measurement is displayed as pulse rate.



## Navigating in Cardiac Output mode

### Areas of the Display

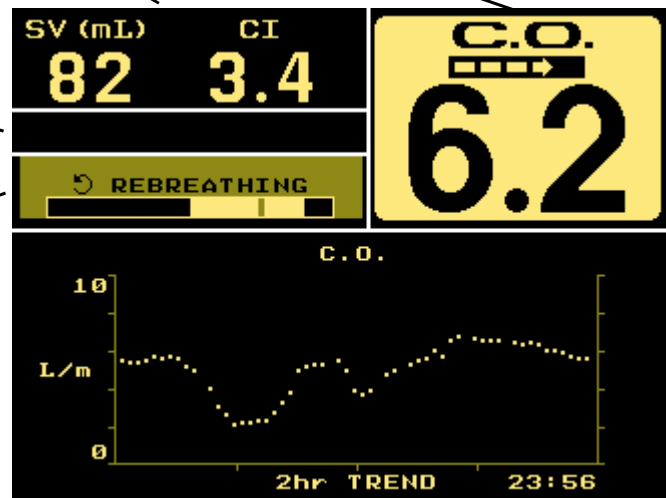
The major sections of the Cardiac Output mode screen are identified below.

Stroke Volume (SV) and Cardiac Index (CI) are displayed in all views. A battery icon also appears if on battery power.

Cardiac Output (C.O.) value is displayed in all views. The CObar™ confidence indicator is replaced by **FAST MODE** when in fast mode.

A General Message area for status, alert and error information. Displayed in all views (here shown blank).

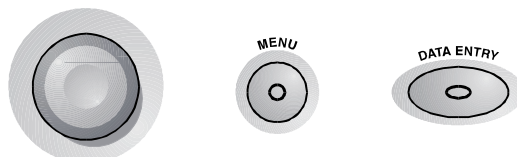
A Cardiac Output Message area for C.O. information is displayed in all views. The Rebreathing Bar is displayed during the rebreathing portion of the cycle.



The lower half of the display presents trend, waveform, respiratory and numeric data to the user. Various data entry, setup and alert menus are also presented here. Use the **KNOB** and the **MENU** and **DATA ENTRY** keys to select the various displays.

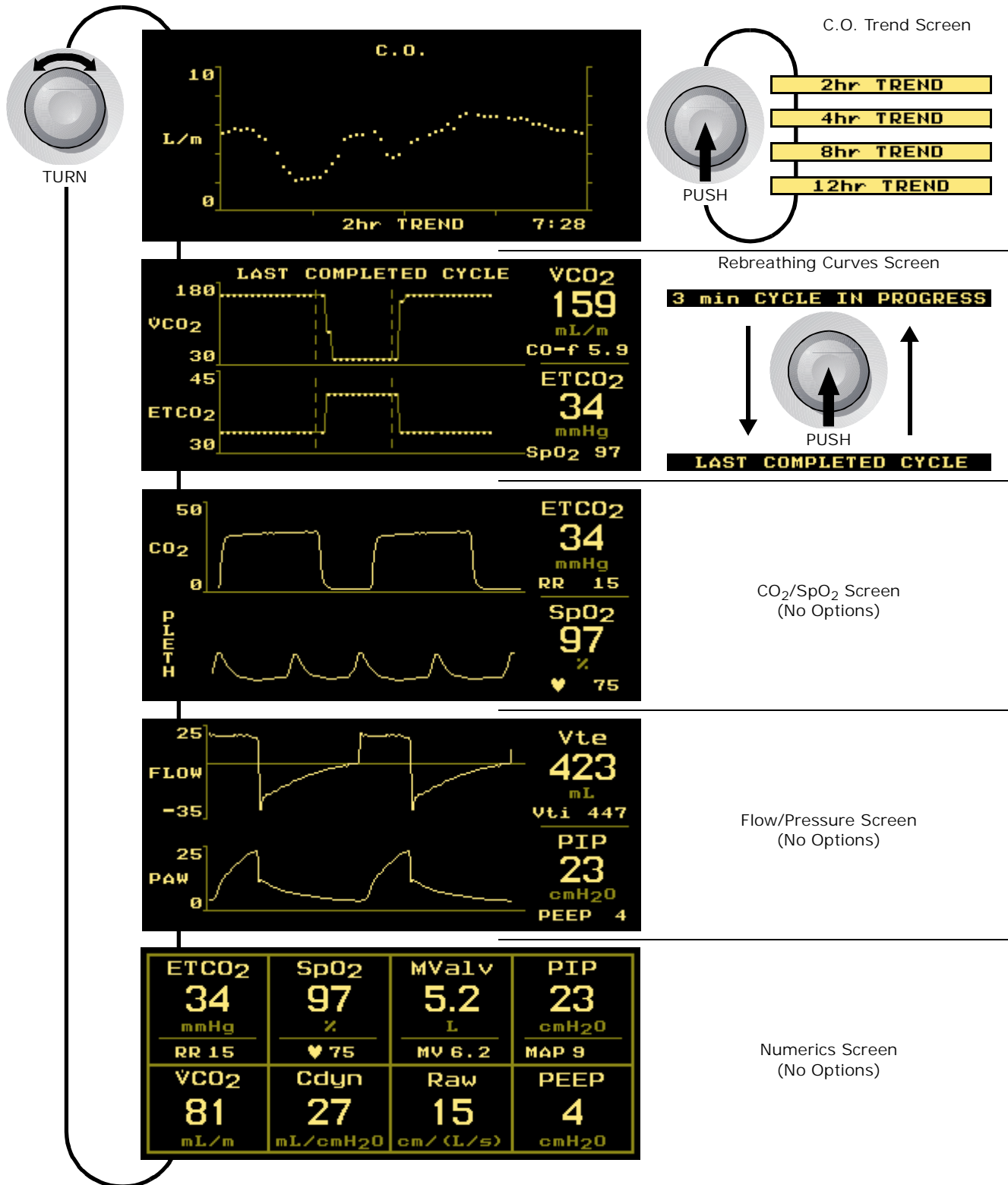
### Navigating the Display System

Use the **KNOB**, **MENU**, and **DATA ENTRY** keys to navigate the NICO® display system (as outlined in the following sections).



## KNOB selectable Monitoring Screens

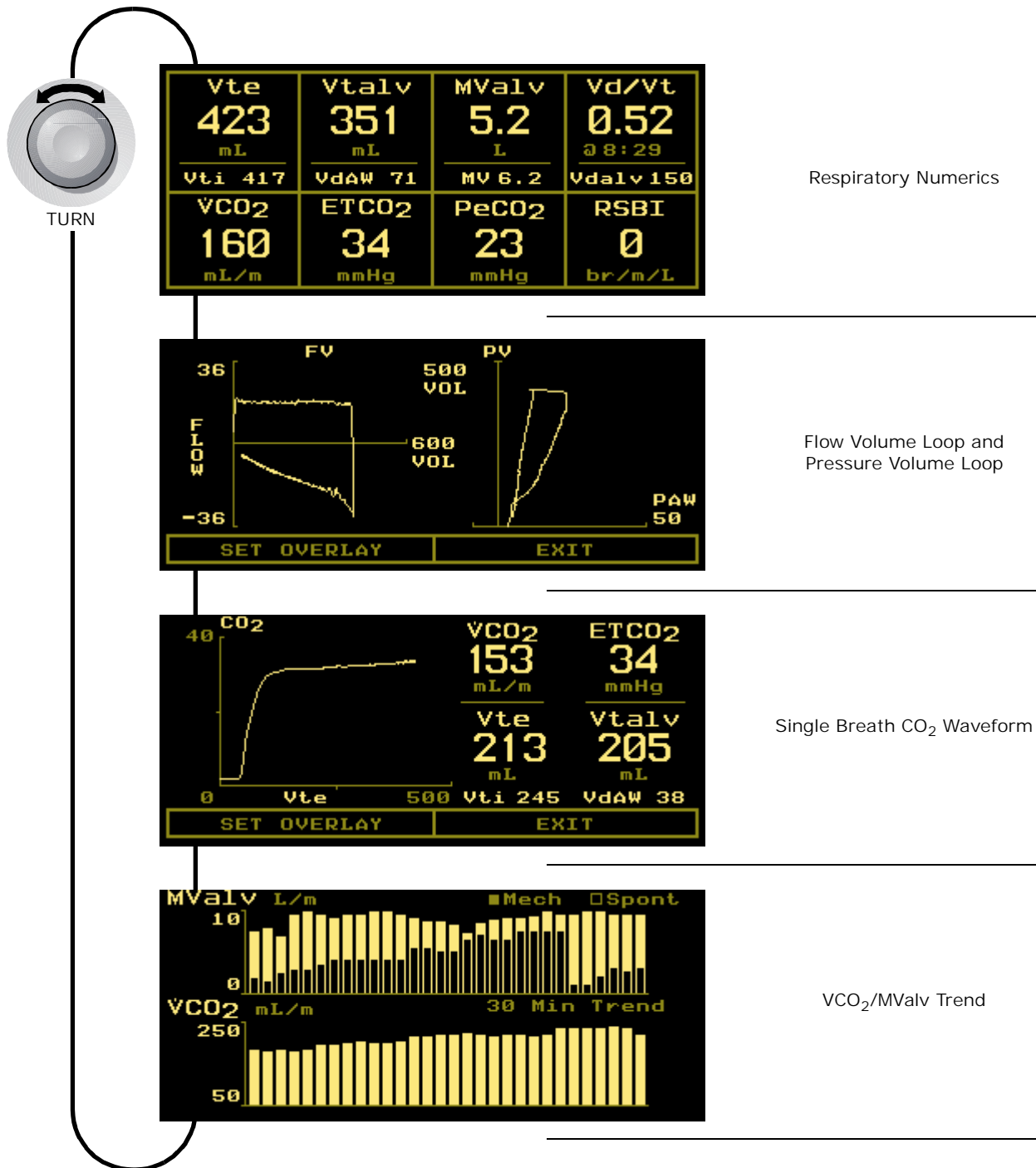
The **KNOB** is used to page through monitoring screens, scroll through menus and make selections, and to change or enter values. The **KNOB** is generally turned to access different monitoring screens and to highlight menu options, and pressed to accept or change selections.



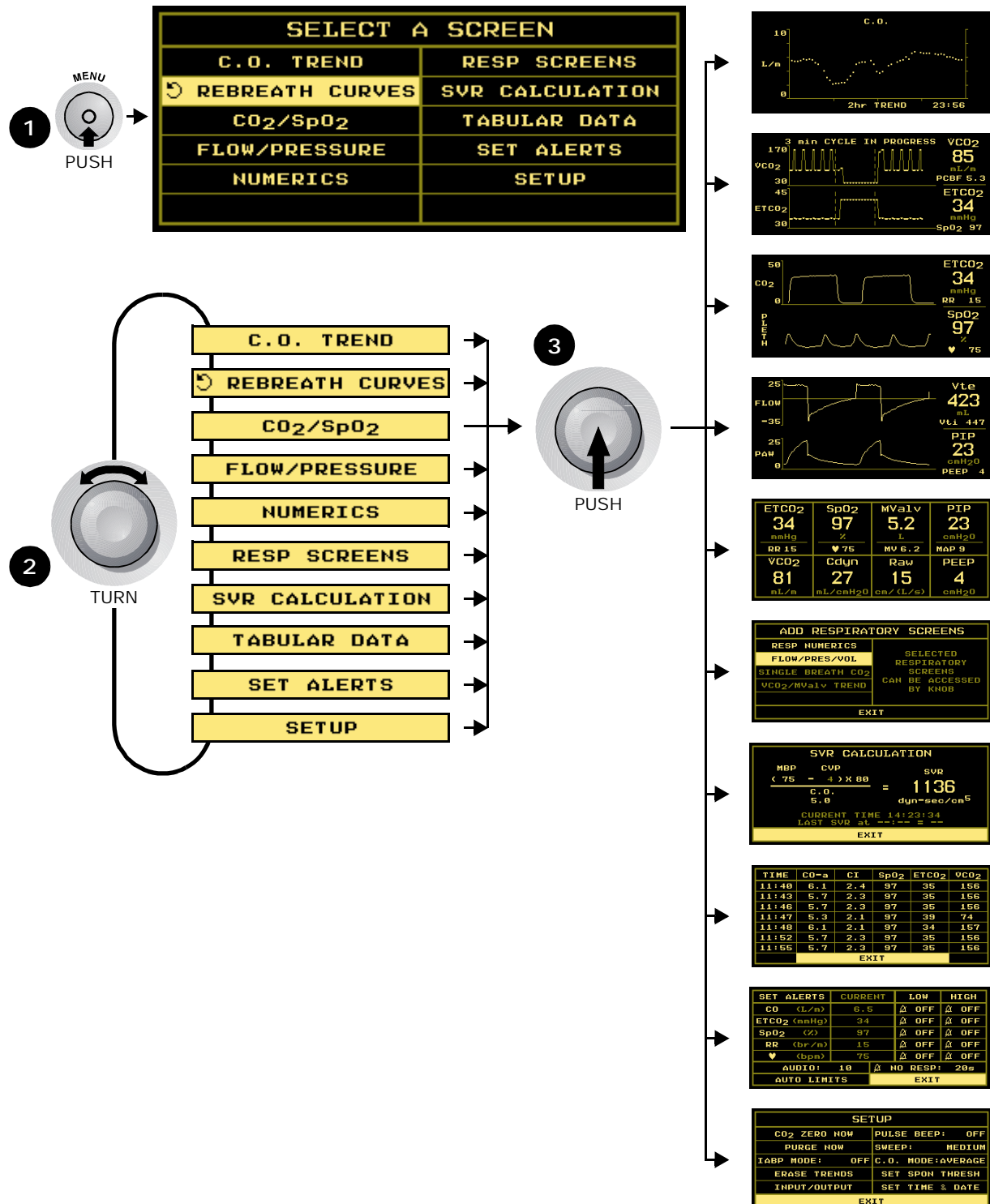
## KNOB Selectable Respiratory Screens

The following Respiratory Screens are available in the monitoring mode **only** when activated. Press the **MENU** key and select **RESP SCREENS** from the **SELECT A SCREEN** menu by turning and then pressing the **KNOB**.

From the **ADD RESPIRATORY SCREENS** menu, highlight and then select which screens will appear in the base monitoring mode by turning and then pressing the **KNOB**. When enabled, selected screens can be displayed by turning the **KNOB** while viewing any monitoring screen.

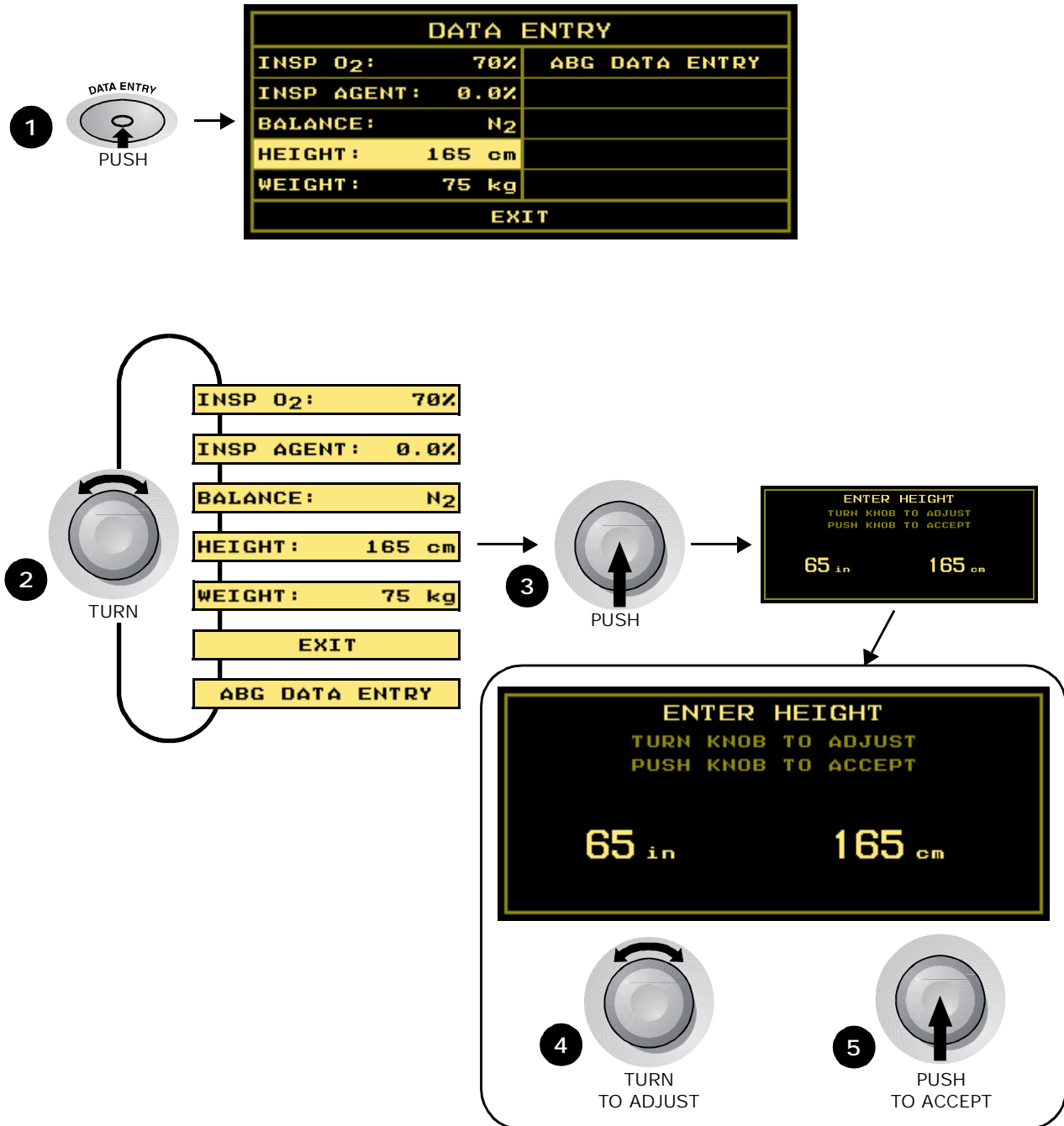


Press the **MENU** key to activate the **SELECT A SCREEN** menu and illuminate the key's green icon. Press the key again to return to the previously displayed screen. From the **SELECT A SCREEN** menu turn the **KNOB** to highlight the screen you wish to display. Press the **MENU** key or the **KNOB** to display that selected screen.



## DATA ENTRY key Screen Displays

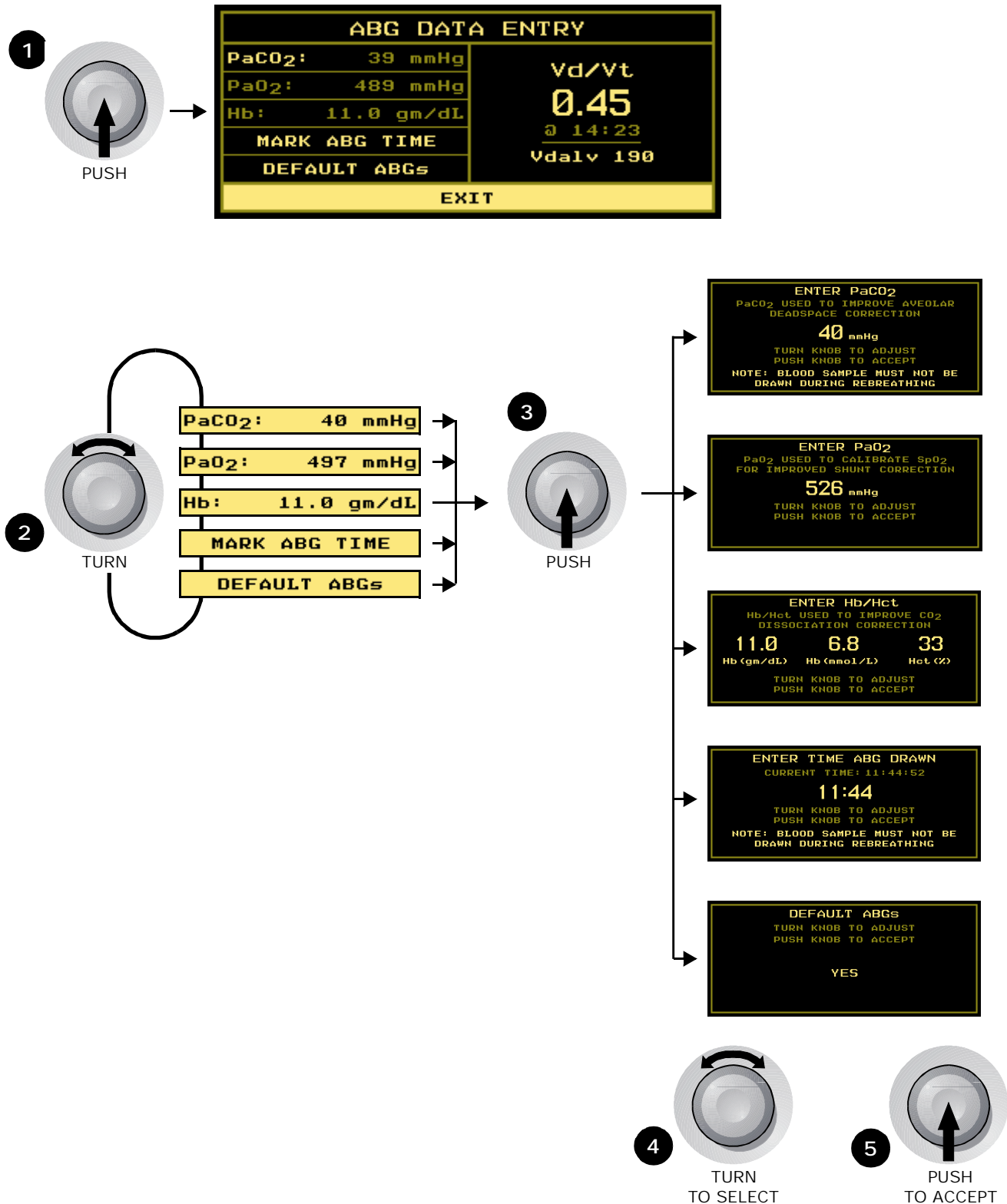
Press the **DATA ENTRY** key to activate the **DATA ENTRY** screen and illuminate the key's green icon. Press the key again to return to the previously displayed screen. From the **DATA ENTRY** screen, you can enter patient information including height, weight and respiratory gas mixture, and access the **ABG DATA ENTRY** screen. (See "Entering Patient Data" on page 28 for details.)



DATA ENTRY key Screen Displays

ABG Data Entry Screens

From the **DATA ENTRY** screen, select **ABG DATA ENTRY**. Turn and press the **KNOB** to enter PaCO<sub>2</sub>, PaO<sub>2</sub>, and Hemoglobin entry screens. (See "Entering Patient Data" on page 28 for details.)

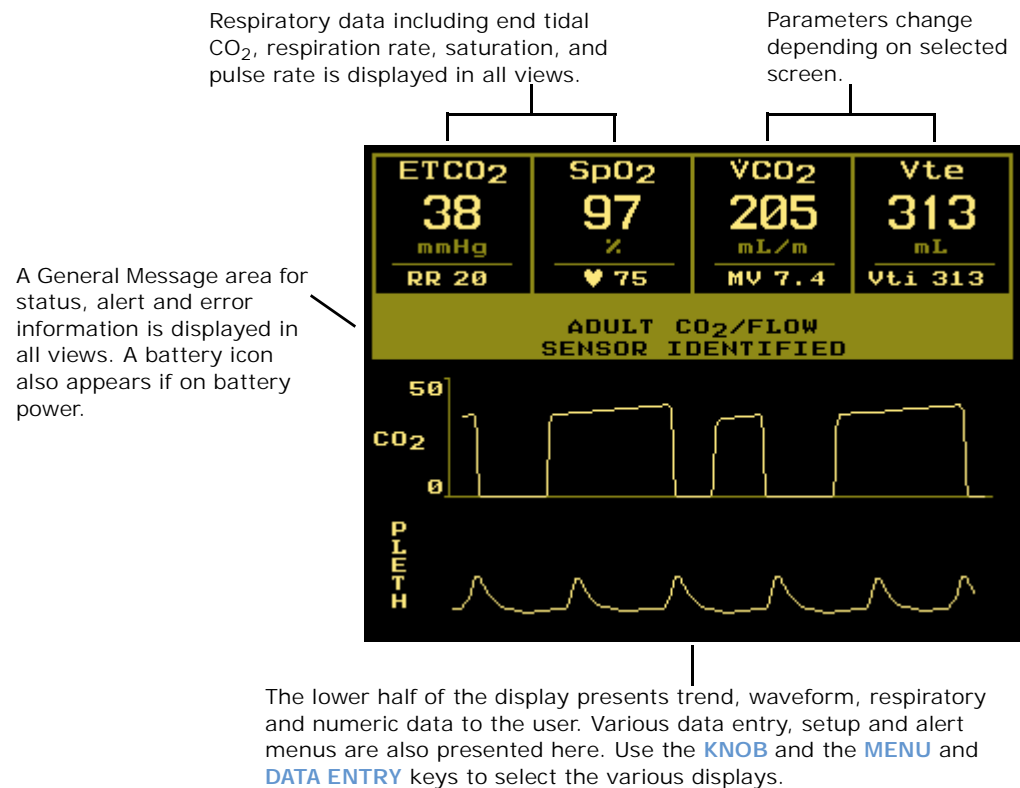




## Navigating in Respiratory Mechanics mode

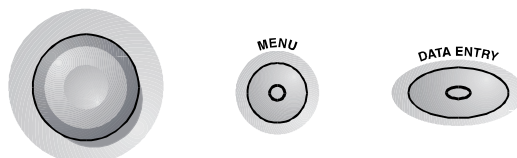
### Areas of the Display

The major sections of the Respiratory Mechanics mode screen are identified below.



### Navigating the Display System

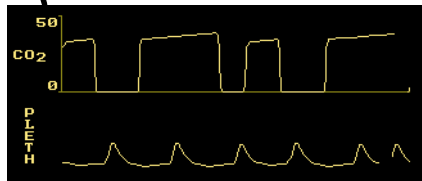
Use the **KNOB**, **MENU**, and **DATA ENTRY** keys to navigate the NICO® display system (as outlined in the following sections).



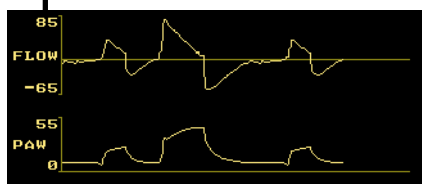


## KNOB selectable Monitoring Screens

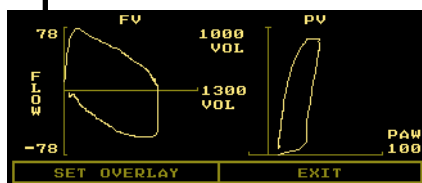
The **KNOB** is used to page through monitoring screens, scroll through menus and make selections, and to change or enter values. The **KNOB** is generally turned to access different monitoring screens and to highlight menu options, and pressed to accept or change selections.



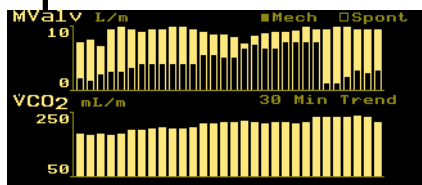
CO<sub>2</sub>/SpO<sub>2</sub> Screen



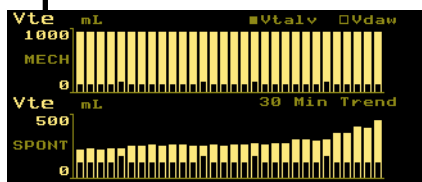
Flow/Pressure Screen



Flow Volume Loop and  
Pressure Volume Loop



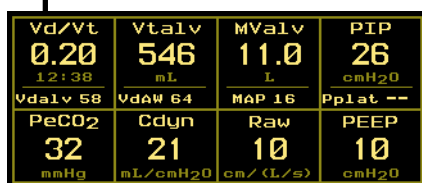
VCO<sub>2</sub>/MValv Trend



Vtalv/Vdaw Trend



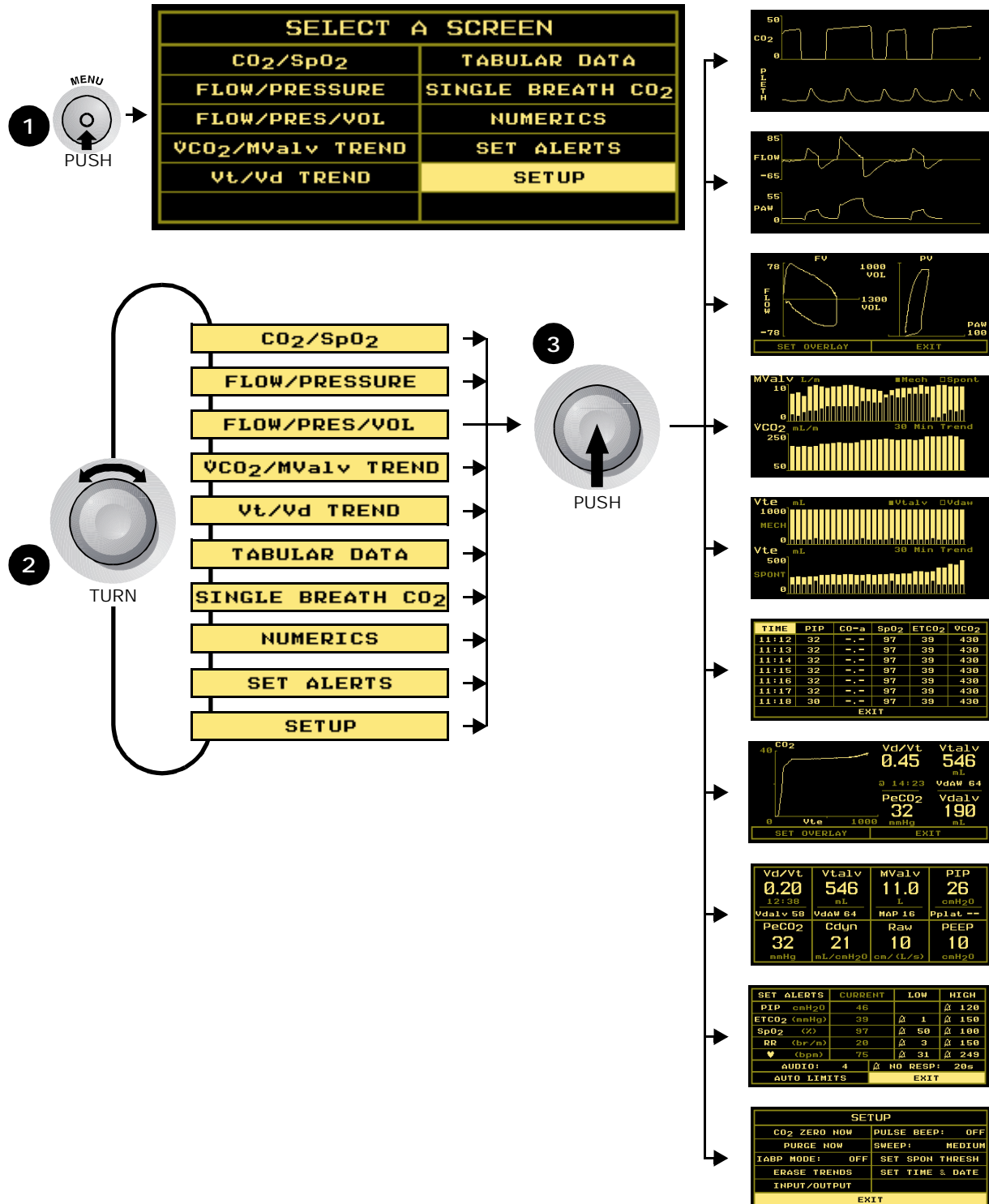
Single Breath CO<sub>2</sub> Screen



Respiratory Numerics Screen

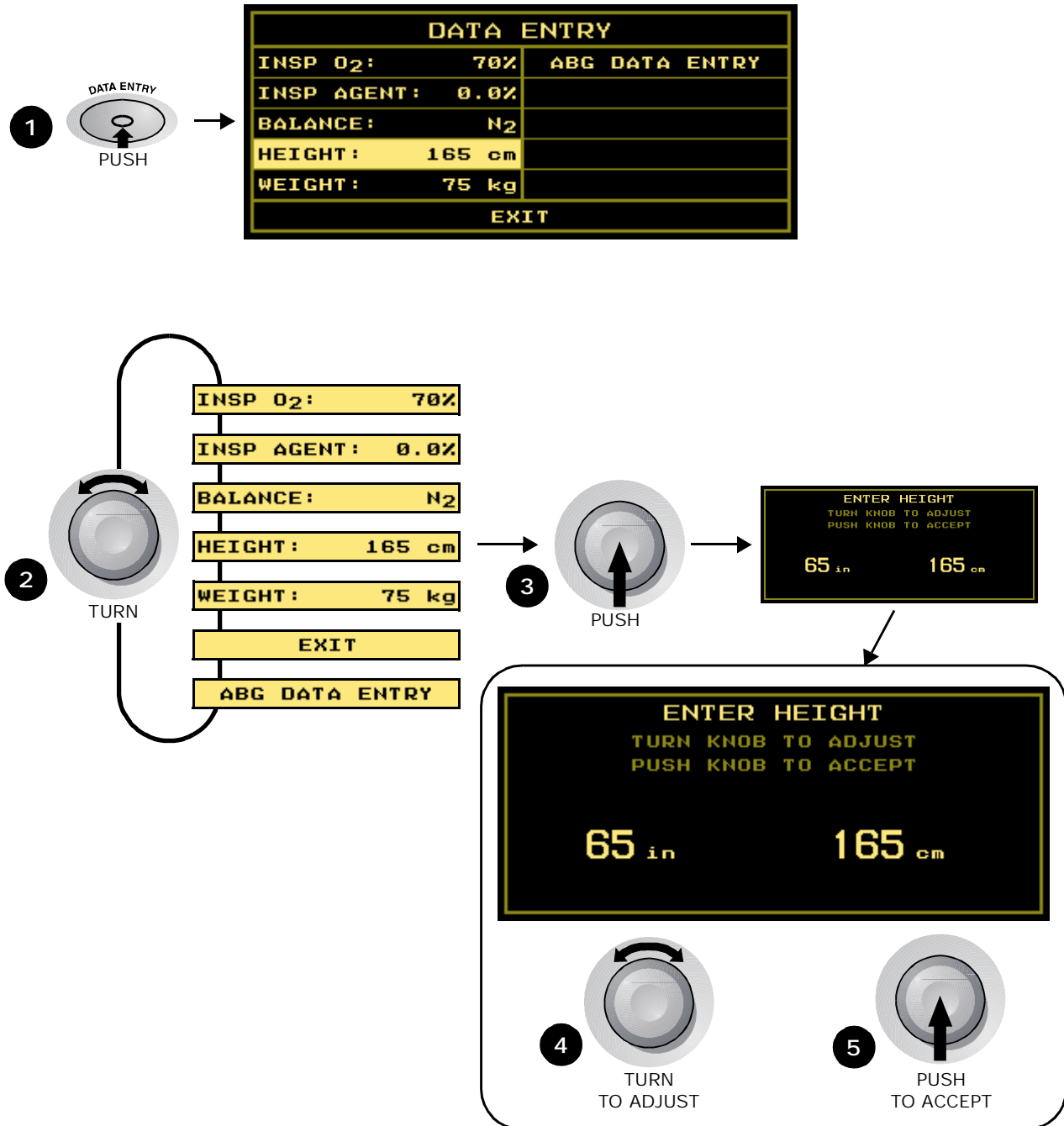
## MENU key Screen Displays

Press the **MENU** key to activate the **SELECT A SCREEN** menu and illuminate the key's green icon. Press the key again to return to the previously displayed screen. From the **SELECT A SCREEN** menu turn the **KNOB** to highlight the screen you wish to display. Press the **MENU** key or the **KNOB** to display that selected screen.



## DATA ENTRY key Screen Displays

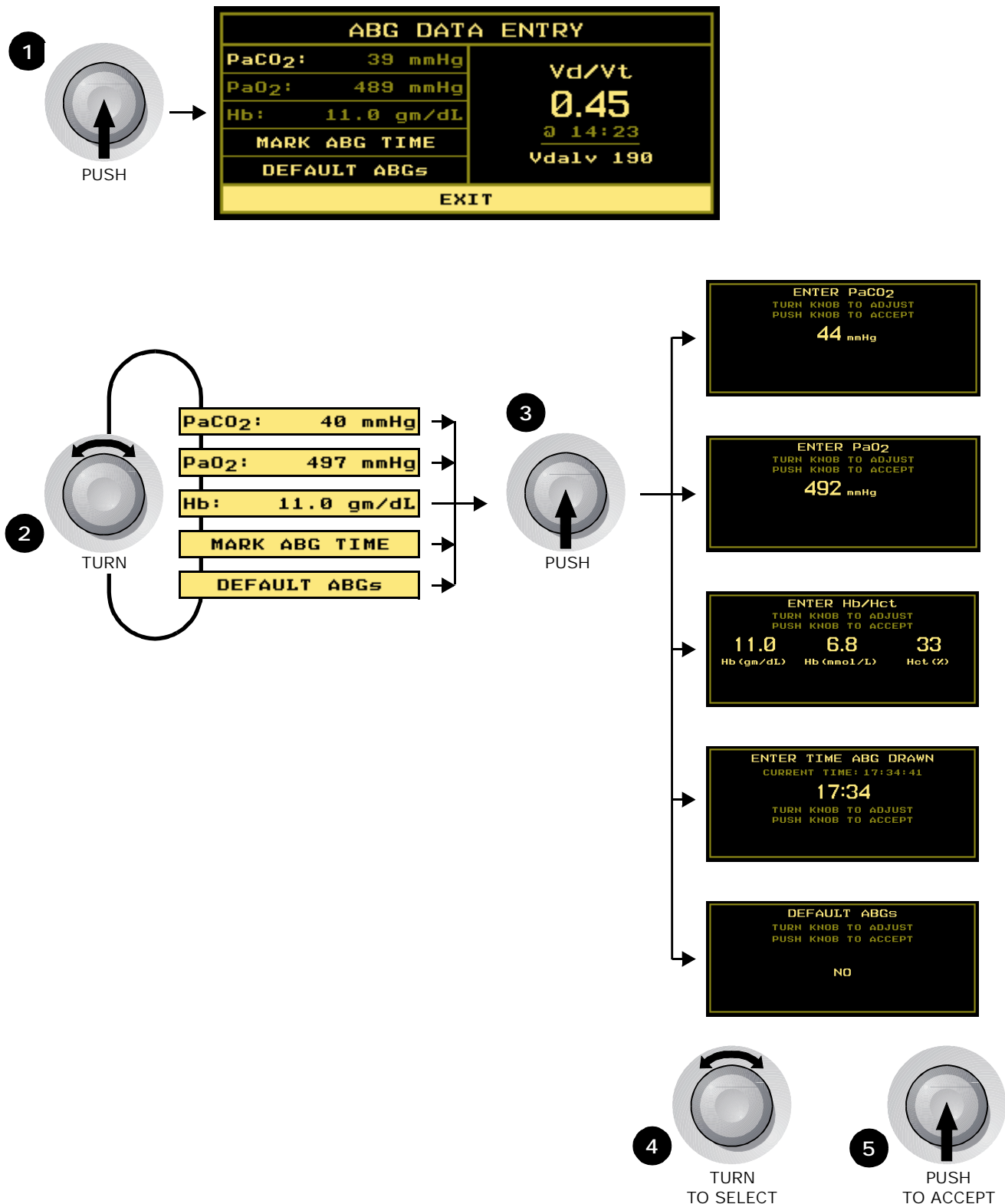
Press the **DATA ENTRY** key to activate the **DATA ENTRY** screen and illuminate the key's green icon. Press the key again to return to the previously displayed screen. From the **DATA ENTRY** screen, you can enter patient information including height, weight and respiratory gas mixture, and access the **ABG DATA ENTRY** screen. (See "Entering Patient Data" on page 28 for details.)



DATA ENTRY key Screen Displays

ABG Data Entry Screens

From the DATA ENTRY screen, select ABG DATA ENTRY. Turn and press the KNOB to enter PaCO<sub>2</sub>, PaO<sub>2</sub>, and Hemoglobin entry screens. (See "Entering Patient Data" on page 28 for details.)





## Safety

For maximum patient and operator safety, observe the following warnings, cautions and notes.

### Warnings



#### **WARNING:**

Indicates a potentially harmful condition that can lead to personal injury.

- Explosion Hazard: Do not use the NICO<sup>®</sup> monitor in the presence of flammable anesthetics. Use of this instrument in such an environment may present an explosion hazard.
- Electrical Shock Hazard: Always turn the NICO<sup>®</sup> monitor off before cleaning it. Do not use with a damaged external power source. Refer servicing to qualified service personnel.
- Connect the AC Mains power cord to a properly grounded hospital-grade outlet. The NICO<sup>®</sup> monitor should be connected to the same electrical circuit as other equipment in use on the patient. Outlets of the same circuit can be identified by members of the hospital's engineering department.
- Failure of Operation: If the monitor fails to respond as described, do not use it until the situation has been corrected by qualified personnel.
- Reuse (disassembly, cleaning, disinfecting, resterilizing, etc.) of the CO<sub>2</sub>, CO<sub>2</sub>/Flow and NICO Sensors<sup>™</sup> may compromise device functionality and system performance and cause a potential patient hazard. Performance is not guaranteed if a sensor is reused.
- Inspect the CO<sub>2</sub>, CO<sub>2</sub>/Flow, SpO<sub>2</sub> and NICO Sensors<sup>™</sup> prior to use.
  - Do not use if they appear to be damaged or broken.
  - Do not attempt to rotate the NICO Sensor<sup>™</sup> in the breathing circuit by grasping the pneumatic tubes exiting the flow sensor.
  - Do not apply excessive tension to any cable or pneumatic tubing.
  - Periodically inspect sensor tubing lines for kinks.
  - Replace the CO<sub>2</sub>, CO<sub>2</sub>/Flow, or NICO Sensor<sup>™</sup> if excessive moisture or secretions are observed in the tubing.
- NICO<sup>®</sup> automatically identifies the type of sensor (small, standard or large NICO Sensor<sup>™</sup>, or neonatal, pediatric or adult CO<sub>2</sub>/Flow sensor ) when it is connected. If a sensor identification message is not displayed when a sensor is first connected, DO NOT use the sensor. If the condition persists, refer the monitor to qualified service personnel.
- Do not use the NICO<sup>®</sup> monitor if it is unable to properly identify a CO<sub>2</sub>/Flow sensor or a NICO Sensor<sup>™</sup>. If the condition persists, refer the monitor to qualified service personnel.
- In the event the message **NICO SENSOR FAILURE** is displayed, remove the NICO Sensor<sup>™</sup> from the patient circuit.
- The CO<sub>2</sub>/Flow or NICO Sensor<sup>™</sup> connector should be properly inserted into the front panel receptacle prior to connecting a sensor to the breathing circuit, in order to avoid a circuit leak, or occlusion of sensor tubing.
- NICO Sensors<sup>™</sup> increases airway deadspace by 35 cc (minimum). At low tidal volumes, compensatory changes to ventilation protocol should be considered.
- NICO Sensors<sup>™</sup> are not for pediatric use.

- Patient Safety: Care should be exercised to assure continued peripheral perfusion distal to the SpO<sub>2</sub> sensor site after application.
  - Inspect the SpO<sub>2</sub> sensor site for adequate circulation at least once every four hours.
  - When applying sensors take note of patient's physiological condition. For example, burn patients may exhibit more sensitivity to heat and pressure and therefore additional consideration such as more frequent site checks may be appropriate.
- Periodically check sensors and tubing for excessive moisture or secretion build up. Although NICO® automatically purges the lines, excessive moisture or secretions may still remain.
- While using the sensors, a system leak, such as that caused by uncuffed endotracheal tubes or a damaged sensor may significantly affect flow related readings. These include flow, volume, pressure, deadspace, CO<sub>2</sub> production and other respiratory mechanics parameters.
- Do not position sensor cables or tubing in any manner that may cause entanglement or strangulation.
- The NICO® monitor is not intended to be used as an apnea monitor.
- The NICO® monitor has no protection against the ingress of water.

## Cautions



### CAUTION:

Indicates a condition that may lead to equipment damage or malfunction.

- Use only Novamatrix approved sensors and accessories with the NICO® monitor.
- Do not operate the NICO® monitor when it is wet due to spills or condensation.
- Do not operate the product if it appears to have been dropped or damaged.
- Never sterilize or immerse the monitor in liquids.
- Do not sterilize or immerse sensors except as directed in this manual.
- No tension should be applied to any sensor cable or tubing.
- To avoid the effects of excessive moisture in the NICO Sensor™, insert it in the ventilator circuit with the pneumatic tubes upright. Excessive moisture in the NICO Sensor™ may affect the accuracy of the measurements.
- To avoid the effects of excessive moisture in the measurement circuit, insert the CO<sub>2</sub>/Flow sensor in the ventilator circuit with the tubes upright. Improper placement may result in erroneous data.
- Excessive moisture in the CO<sub>2</sub>/Flow sensor tubing may affect the accuracy of the measurements.
- It is recommended that CO<sub>2</sub>/Flow or NICO Sensors™ be removed from the circuit whenever an aerosolized medication is delivered. This is due to the increased viscosity of the medications which may contaminate the sensor windows, causing the sensor to fail prematurely.
- Operate the monitor at temperatures between 10 to +40° C (50 to 104° F), 10-95% R.H. non-condensing.
- Avoid storing the monitor at temperatures less than -10° C or greater than +55° C (<14° F or >131° F) 10-95% R.H. non-condensing
- Observe precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from other equipment.
- Where electromagnetic devices (i.e., electrocautery) are used, patient monitoring may be interrupted due to electromagnetic interference. Electromagnetic fields up to 3 V/m will not adversely affect system performance.
- Caution: Federal (U.S.A.) law restricts this device to sale, distribution, or use by or on the order of a licensed medical practitioner.

## Notes

### NOTE

A point of particular interest or emphasis intended to provide more efficient or convenient operation.

- In order to ensure proper monitoring of oxygenation and ventilation:
  - The use of pulse oximetry is recommended during NICO® monitoring.
  - Setting of ETCO<sub>2</sub> and SpO<sub>2</sub> alert limits is recommended.
- A “NO RESPIRATION” alert is not generated when both the CAPNOSTAT® CO<sub>2</sub> sensor and the NICO Sensor™ or CO<sub>2</sub>/Flow sensor are disconnected from the NICO® monitor.
- Be certain that the monitor is not in Demo mode while monitoring. Demo mode can be identified by the flashing **DEMO MODE** label in the General Message area of the display. To exit Demo mode and return to normal monitoring mode, turn the power off and back on.
- The NICO® monitor contains no user serviceable parts. Refer servicing to qualified service personnel. A technical Service Manual is available for use by technical personnel.
- Do not attach an SpO<sub>2</sub> sensor distal to a blood pressure cuff. Valid data cannot be processed when the cuff is inflated. Attach the sensor to the limb opposite to the site used for the blood pressure cuff.
- This product and its accessories which have patient contact are free of latex.
- The NICO® monitor is Year 2000 compliant.
- Data Validity: Inaccurate SpO<sub>2</sub> and Pulse Rate values may be caused by:
  - Incorrect application or use of a sensor
  - Significant levels of dysfunctional hemoglobin; carboxyhemoglobin or methemoglobin
  - Significant levels of indocyanine green, methylene blue, or other intravascular dyes
  - Exposure to excessive illumination such as surgical lamps—especially ones with a xenon light source, or direct sunlight
  - Excessive patient movement
  - Venous pulsations
  - Electrosurgical interference
  - Use of an IABP.
- NICO® measurements will occur provided the following conditions are met:
  - The NICO Sensor™ assembly is properly installed in the patient’s breathing circuit.
  - Valid flow and CO<sub>2</sub> signals are detected with no significant signal artifact.
  - VCO<sub>2</sub> is greater than 20 mL/min.
  - ETCO<sub>2</sub> is between 15 and 85 mmHg (2.0 - 11.5 kPa or %) during baseline
  - ETCO<sub>2</sub> is between 15 and 100 mmHg (2.0 - 13.5 kPa or %) during rebreathing
  - The tidal volume is greater than 200ml (small and standard sizes)
  - The tidal volume is greater than 400 ml (large size).
  - The respiratory rate is between 3 and 60 br/min.
  - The **STOP/CONTINUE REBREATHING** key is not illuminated.
  - NICO® is not paused by the monitor for any other reason (displayed in the C.O. message area)
- When a new CAPNOSTAT® CO<sub>2</sub> sensor is attached to the monitor, or is moved from one monitor to another, it must be zeroed before use.
- After the life cycle of the equipment and accessories has been met, disposal should be accomplished following national and local requirements.



## Monitoring Cardiac Output

This section details the steps needed to begin patient monitoring with the NICO® monitor.

### Preparing for Use

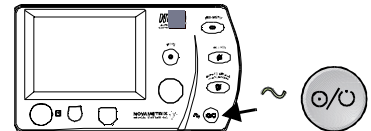
#### Inspect

Before monitoring, take a few moments to inspect the NICO® monitor and its sensors. Check that all items are clean, dry, and physically intact with no broken or damaged components.

#### Turn on the monitor

Turn the NICO® monitor on.

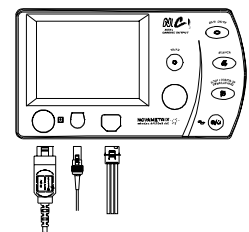
- 1 Press the **Operate/Standby** key to turn the monitor on and off.
  - NICO® can operate from its internal battery or from the AC Mains. (See "AC/Battery Operation" on page 4 for details.)
- 2 The monitor performs a quick self-test.
  - An audible tone sounds, the key indicators illuminate, and a **SELF-TEST IN PROGRESS** message is briefly displayed.
- 3 The message **PRESS KNOB TO ERASE STORED TRENDS** is displayed for 5 seconds.
  - To erase the contents of the monitor's trend memory, press the knob. **TRENDS ERASED** is briefly displayed.
  - To retain the contents of the monitor's trend memory, do not press the knob. Wait the 5 seconds and **TRENDS RETAINED** is displayed.
  - Note: If the internal battery becomes fully discharged, the message **CHECK DATE/TIME (MENU -> SETUP)** will appear before the **PRESS KNOB TO ERASE STORED TRENDS** message. (See "Setup Screen" on page 45 for details.)
- 4 The power up sequence is completed and a monitoring screen is displayed.
  - NICO® displays the screen that was displayed when the monitor was last turned off.
  - If the monitor is in Respiratory Mechanics mode, connecting a NICO Sensor™ will cause the monitor to automatically switch to Cardiac Output mode.
  - The monitor is in a READY state and the parameters will be dashed and alerts will not be active until parameters are calculated and displayed.
  - Parameters will display and their alerts will become active as they are calculated.



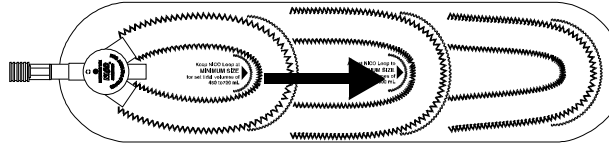
#### Connect and apply the sensors

Connect the sensors to the monitor, ventilator circuit, and patient.

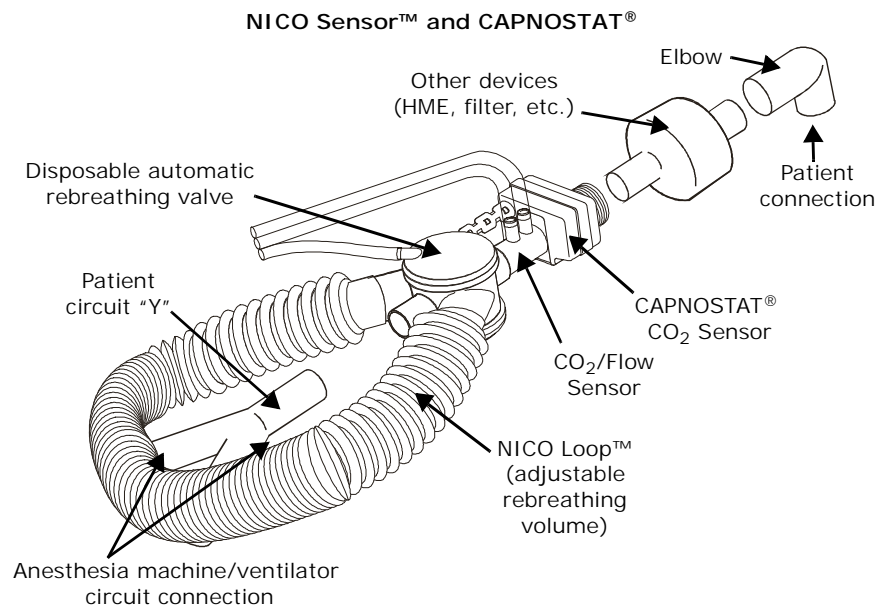
- 1 Connect the SpO<sub>2</sub> sensor to the monitor and apply it to the patient. (See "Pulse Oximetry Sensors" on page 67.)
- 2 Connect the CAPNOSTAT® CO<sub>2</sub> Sensor to the monitor. (See "CAPNOSTAT® CO<sub>2</sub> Sensor" on page 65.)
- 3 Select a NICO Sensor™, see "Choosing a NICO Sensor™ size" on page 60.
- 4 Connect the NICO Sensor™ to the monitor and attach a CAPNOSTAT®. (See "NICO Sensor™" on page 59.)
- 5 Use the Initial Adjustment Template as a guide and adjust the NICO Loop™ to match the ventilator's tidal volume setting, then discard the template. (See Instructions on the NICO® template.










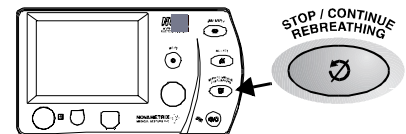
- 6 For optimal results, place the NICO Sensor™ into the ventilator circuit between the endotracheal tube and the ventilator circuit wye.
  - Place other devices (HME, filters, etc.) between NICO Sensor™ and the patient connection.
  - The NICO Sensor™ increases airway deadspace by 35 cc (minimum). At low tidal volumes, compensatory changes to ventilation protocol should be considered.
  - Placement of a sidestream gas analyzer sampling port between the NICO Sensor™ and the patient connection may reduce NICO® accuracy at low tidal volumes.
  - Sidestream or mainstream gas analyzers placed between the NICO Sensor™ and the patient circuit “Y” may be inaccurate during the rebreathing phase of the NICO® cycle.
  - Place the sensor so that the triple lumen tubing lines exit from the top of the sensor (to help keep them clear and dry).
  - Keep the sensor clear of accumulations by proper circuit maintenance.



## Begin NICO® monitoring

After the NICO® monitor is turned on and the sensors are properly connected and applied, cardiac output monitoring can begin.

- 1 Press the **STOP/CONTINUE REBREATHING** key to initiate monitoring. Subsequent presses will Stop/Continue the rebreathing process.
  - An icon “” identifies rebreathing status.
  -  Illuminated: Rebreathing is DISABLED.
  -  Not illuminated: Rebreathing is ENABLED.




- 2 Enter the patient's height and weight (for cardiac index calculations) and the delivered oxygen, anesthetic agent and balance gas by pressing the **DATA ENTRY** key. (See “Entering Patient Data” on page 28.)
- 3 If available, enter the patient's PaCO<sub>2</sub>, PaO<sub>2</sub>, hemoglobin and hematocrit in the **ABG DATA ENTRY** screens, then mark the ABG time before exiting. (See “Entering Patient Data” on page 28.)

NOTE: Vd/Vt Phy, Vd Phy, and Vd alv are calculated based on the PaCO<sub>2</sub> value last entered, and are not updated until the next time the PaCO<sub>2</sub> value is entered or changed.

4 As you begin monitoring with NICO®, please note the following:

- Reliance on Cardiac Output parameters (NICO®, SV & CI) should be taken in context with other monitoring parameters and the physiologic condition of the patient.
- Entry of patient height and weight is required to calculate and display Cardiac Index.
- Pulse oximetry is required to calculate and display Stroke Volume (SV).
- Accuracy of cardiac output and related parameters will be affected by the following:
  - Significant fluctuations in mixed venous CO<sub>2</sub> content or metabolic CO<sub>2</sub> production during any three minute measurement period.
  - Sudden release of CO<sub>2</sub> into the bloodstream, such as when releasing a cross clamp.
  - The presence of excessive moisture or secretions in the NICO® sensor.
  - Entry of blood gas information.
- Due to the periodic rebreathing for NICO® measurements, the patient's effective ventilation will be reduced by typically 10-15% (depending on the rebreathing volume required). This can be offset by increasing the minute ventilation before NICO® monitoring begins.

### Rebreathing Bar

The Rebreathing Bar visually indicates the level of patient rebreathing. Under normal monitoring conditions, the  **REBREATHING** icon and Rebreathing Bar appear in the message center each time the automatic rebreathing cycle begins.



- The Rebreathing Bar represents the total possible range of rebreathing from 0-100%.
- The highlighted area within the bar represents the target rebreathing range (50%-90%) for optimal NICO® performance.
- A vertical pointer within the Rebreathing Bar indicates the current rebreathing percentage.
  - The pointer will appear within the highlighted area of the Rebreathing Bar when the NICO Loop™ is properly sized and providing an acceptable percentage of rebreathing.
  - *Note:* The word "OK" will disappear when the pointer falls within that area of the highlighted bar.
- The Rebreathing Bar is not displayed when the ratio of spontaneous to mechanical breaths is greater than or equal to 2:1.

### Expand/Retract NICO Loop™

- If the NICO Loop™ is not sufficiently expanded and the Rebreathing Bar pointer falls below 50%, the message **EXPAND LOOP** is displayed during the rebreathing period.
- If the NICO Loop™ is over-expanded and the Rebreathing Bar pointer is above 90%, the message **RETRACT LOOP** is displayed during the rebreathing period.



To expand or retract the NICO Loop™:

- 1 Grasp the NICO Loop™ with one hand and the automatic rebreathing valve with the other hand so as not to disturb/disconnect the breathing circuit while adjusting the loop.
- 2 Expand or retract the NICO Loop™ 3-6 inches.
  - It may take 2-3 additional breaths before the icon changes.
  - Note that if the loop is still not appropriately sized by the end of the rebreathing period, the message will be removed and may be displayed again during the next rebreathing period.

### Sensor Size Message

If the **EXPAND** or **RETRACT LOOP** message appears for more than three rebreathing cycles, and resizing the NICO Loop™ was not effective, the NICO® monitor will suggest a different sized sensor to correct the condition. See "Status Messages" on page 61.



### The NICO® Cycle

Once rebreathing is enabled, the NICO® monitor automatically repeats a three minute cardiac output measurement cycle. This NICO® cycle has three phases:

- **Baseline:** During the 60-seconds baseline period the rebreathing valve inside the NICO Sensor™ is turned off and the rebreathing volume of the NICO Loop™ is bypassed. During this time, VCO<sub>2</sub>, PaCO<sub>2</sub> and ETCO<sub>2</sub> will be at baseline values.
- **Rebreathing:** The 50-second rebreathing period starts when the monitor turns on the rebreathing valve inside the NICO Sensor™ causing the rebreathing volume of the NICO Loop™ to be added into the circuit. During rebreathing, VCO<sub>2</sub> is reduced, PaCO<sub>2</sub> and ETCO<sub>2</sub> become elevated (3-5 mmHg, typical) and mixed venous CO<sub>2</sub> remains unchanged.

**NOTE:** The rebreathing period will typically induce an increase in PaCO<sub>2</sub> by 3-5 mmHg. An ABG blood sample drawn during this period (🔄 **REBREATHING** displayed) or during the first twenty seconds of the stabilization period (where **NEXT** 🔄 is displayed), may cause PaCO<sub>2</sub> values to reflect higher than normal levels.

- **Stabilization:** After completion of rebreathing, a 70-second stabilization period begins, during which time VCO<sub>2</sub>, PaCO<sub>2</sub> and ETCO<sub>2</sub> return to their baseline values.

NICO® updates the displayed C.O. value following the completion of each three minute NICO® cycle. The CObar™ (cardiac output confidence bar) provides an indication of the system's confidence in the displayed value. (See "CObar™ Confidence Indicator" on page 31.)

### Rebreathing On/Off or Paused

The user can interrupt or resume the rebreathing cycle at any time by pressing the **STOP/CONTINUE REBREATHING** key. The NICO® monitor will not automatically restart the rebreathing cycle—that must be initiated by the user pressing the **STOP/CONTINUE REBREATHING** key. Note that once rebreathing is initiated by the user, the monitor will, under certain conditions, pause rebreathing until a specified condition (see below) is corrected—at which time the monitor will restart the rebreathing.

Rebreathing can be Off, On, or Paused as indicated below:

#### Rebreathing OFF (disabled)

- The NICO® monitor starts in this state upon power-up.
- The **STOP/CONTINUE REBREATHING** key is illuminated while in this state.
- The NICO® rebreathing cycle can be placed into this state at any time by pressing the **STOP/CONTINUE REBREATHING** key (rebreathing is immediately disabled).
- The NICO® rebreathing cycle is automatically turned off for certain monitor/sensor conditions. (See "(Alert Class: H-High Priority, M-Medium Priority, L-Low Priority, S-Status Message. See "NICO® Alert Priorities" on page 56 for details." on page 79.)
- Noted in the cardiac output message area as **REBREATHING OFF**.

**REBREATHING OFF**  
PRESS 🔄 KEY TO  
**CONTINUE**

#### Rebreathing ON (enabled)

- When the monitor is initially turned on, this state is entered only after pressing the **STOP/CONTINUE REBREATHING** key.
- The **STOP/CONTINUE REBREATHING** key is not illuminated while in this state.
- The cardiac output is calculated and updated while in this state.
- Noted in the cardiac output message area as 🔄 **REBREATHING** or **NEXT** 🔄.

🔄 **REBREATHING**  
OK

**NEXT** 🔄: 1:57

#### Rebreathing Paused

- The NICO® monitor automatically pauses the rebreathing cycle and generates a display message under any of these conditions:
  - ETCO<sub>2</sub> is less than 15 mmHg (2.0 kPa or %) or greater than 85 mmHg (11.5 kPa or %)
  - Respiration rate is less than 3 or greater than 60 br/min.
  - VCO<sub>2</sub> is less than 20 mL/min.
- The rebreathing cycle automatically restarts when the condition is corrected.

**REBREATHING PAUSED**  
WAITING FOR  
RR > 3 br/m

## Entering Patient Data

NICO® monitoring can be enhanced by the entry of key patient specific data including respired gas composition (anesthetic agent, balance gas, and inspired O<sub>2</sub>), patient height and weight, and arterial blood gas data (PaCO<sub>2</sub>, PaO<sub>2</sub>, Hb or Hct). Inclusion of ABG data is especially important when gas exchange impairment is expected (i.e., high shunt or deadspace). **ABG samples should not be obtained during the rebreathing phase of the 3-minute NICO® cycle.**

Patient data should be updated in the **DATA ENTRY** screen whenever possible. The screen may be accessed at any time by pressing the **DATA ENTRY** key.

**DATA ENTRY settings** The following table lists the parameters and ranges accessible in the **DATA ENTRY** screens.

Label	Parameter	Default	Range/Units	Description
INSP O <sub>2</sub>	Inspired Oxygen	70%	21-100 %	Percent of oxygen in the inspired gas. Must be entered in order for NICO® to accurately calculate parameters.
INSP AGENT	Inspired Anesthetic Agent	0%	0-20 %	Percent of anesthetic agent in the inspired gas. Must enter percent delivered in order for NICO® to accurately calculate parameters.
BALANCE	Gas Balance	N <sub>2</sub>	N <sub>2</sub> , He, or N <sub>2</sub> O	N <sub>2</sub> , He or N <sub>2</sub> O. Must select the correct balance in the inspired gas in order for NICO® to accurately calculate parameters.
HEIGHT	Patient Height	--	35-91 in 90-230 cm	Enter patient height for CI calculations.
WEIGHT	Patient Weight	--	55-551 lb 25-250 kg	Enter patient weight for CI calculations.
<b>ABG DATA ENTRY Screen</b>				
PaCO <sub>2</sub>	Arterial Carbon Dioxide	40 mmHg (5.4 kPa or %)  ("--" displayed until an initial value is entered)	0-250 mmHg 0.0-20.0 kPa 0.0-20.0 %	Partial pressure of carbon dioxide in arterial blood. Entering this value can enhance the accuracy of NICO® parameters.
PaO <sub>2</sub>	Arterial Oxygen	FiO <sub>2</sub> (Pb-47 mmHg) ("--" displayed until an initial value is entered)	0-750 mmHg 0.0-99.5 kPa 0.0-99.5 %	Partial pressure of oxygen in arterial blood. Entering this value can enhance the accuracy of NICO® parameters.
Hb	Hemoglobin Concentration or Hematocrit	11.0 gm/dL 6.8 mmol/L 33 % ("--" displayed until an initial value is entered)	Hb: 5.0-20.0 gm/dL Hb: 3.1-12.4 mmol/L Hct: 0-60 %	Concentration of hemoglobin or hematocrit in the blood. Entering this value can enhance the accuracy of NICO® parameters.
MARK ABG TIME	Time when ABG blood sample is drawn	Current Time	hh:mm (hours:minutes)	Enter time ABG is drawn. (Only accepts time since ETCO <sub>2</sub> was first detected.)
DEFAULT ABGs	Blood gas values	PaCO <sub>2</sub> : 5 mmHg (0.7 kPa or %) above the measured ETCO <sub>2</sub> value <sup>a</sup>  PaO <sub>2</sub> : Based on barometric pressure and INSP O <sub>2</sub> value.  Hb: 11.0 gm/dL		Resets blood gas settings to default values.

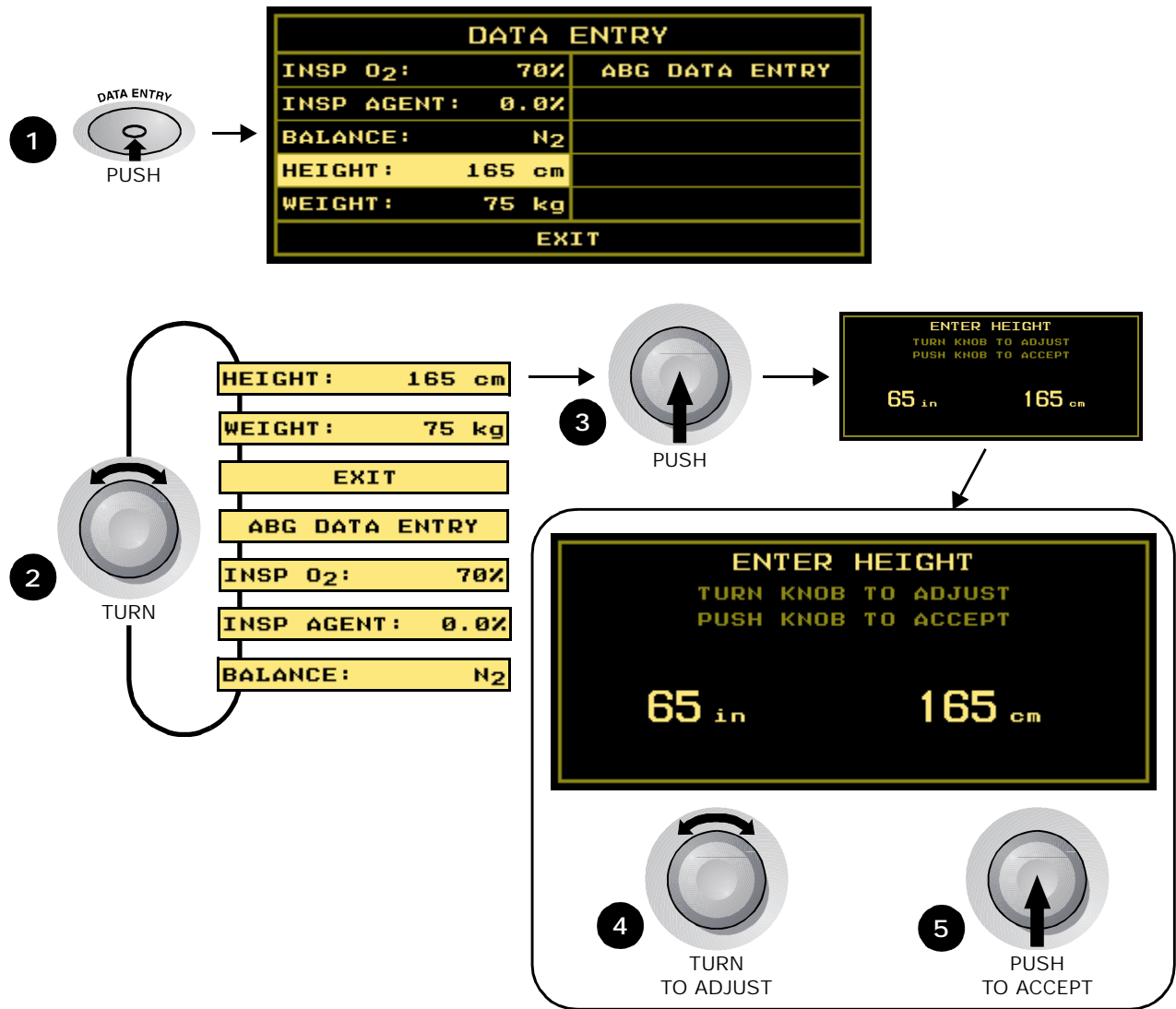
a. 40mmHg (5.4 kPa or %) if ETCO<sub>2</sub> is not available.

## Entering ABG Data

### Entering Patient Data

To enter (or view) patient data:

- 1 Press the **DATA ENTRY** key to activate **DATA ENTRY**. The key's green icon illuminates.
  - Press the key again to return to the previously displayed screen.
- 2 Highlight the desired data by turning the **KNOB**.
- 3 Select the highlighted data by pressing the **KNOB**.
- 4 Turn the **KNOB** to adjust the value as desired.
- 5 Press the **KNOB** to accept the value.
- 6 Repeat these steps for the other settings.



## Entering ABG Data

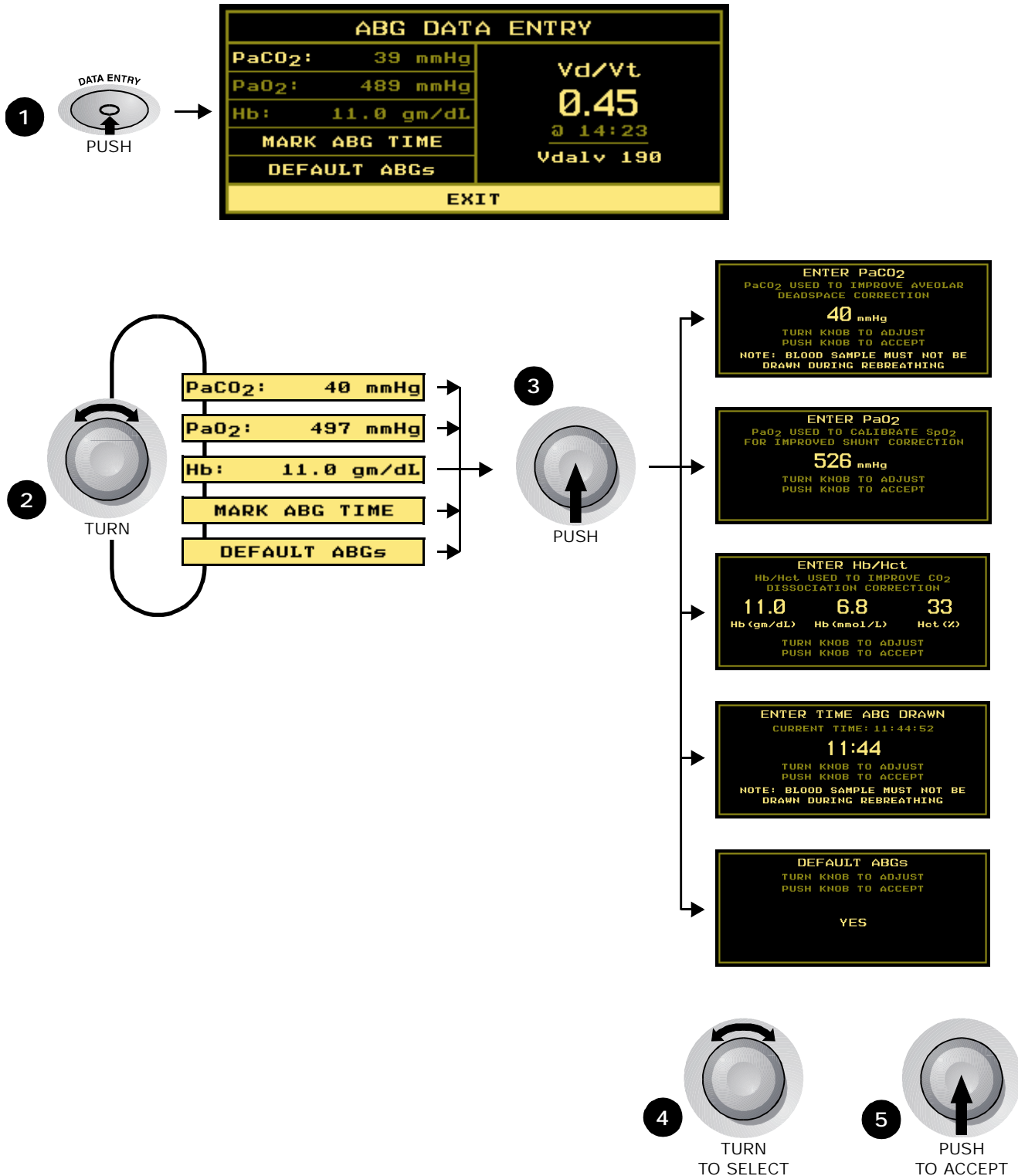
To enter ABG data:

- 1 Draw blood sample during the "normal" phase of the NICO® cycle, not during the rebreathing phase.
  - The cardiac output message will display how much time before the next rebreathing phase occurs.

**NEXT** ⌚: 1:57

Entering ABG Data

- 2 Press the **DATA ENTRY** key to activate **DATA ENTRY**. The key's green icon illuminates.
  - Press the key again to return to the previously displayed screen.
- 3 Highlight **ABG DATA ENTRY** by turning the **KNOB**.
- 4 Select **ABG DATA ENTRY** by pressing the **KNOB**.



- 5 Turn and press the **KNOB** to select the PaCO<sub>2</sub>, PaO<sub>2</sub>, Hb/Hct, Mark ABG Time or Default ABG screen.
- 6 Turn **KNOB** to adjust value.
  - ABG Time is required for PaCO<sub>2</sub> and PaO<sub>2</sub>.
  - Ensure that the NICO® clock is synchronized to the clock used to determine the draw time.
- 7 Press the **KNOB** to accept the value and return to the **ABG DATA ENTRY** screen.
  - Updated Vd/Vt and Vd<sub>alv</sub> values are displayed.

## C.O. Averaging

### CObar™ Confidence Indicator

The Cardiac Output Confidence Bar, or CObar™, is an indicator of the system's confidence in the currently displayed cardiac output value. The CObar indicator is located above the cardiac output value and can contain up to five segments. The degree of confidence (more segments for higher confidence, fewer segments for lower confidence) is based on multiple factors including ventilatory pattern, sizing of the NICO Loop™, tidal volume, entry of patient data and breathing circuit integrity.



At higher confidence levels the system can more quickly resolve changes in C.O. and is therefore able to display those changes more quickly. At lower confidence levels, the system must work harder at resolving C.O. changes, thereby delaying how quickly that information can be displayed. The delay from detection to display of changes in C.O. can range from:

- 5 segments: 1.5 - 2 minutes
- 4 segments: 3 - 7 minutes
- 3 segments: 5 - 9.5 minutes
- 2 segments: 7 - 9.5 minutes
- 1 segment: 8.5 - 9.5 minutes

A lower number of segments indicates that the displayed cardiac output reading is being averaged more with readings from previous NICO® rebreathing cycles.

If there is no confidence in the signals, the C.O. value is not displayed and no segments are displayed in the CObar.

The CObar is displayed when the **C.O. MODE** is set to **AVERAGE** in the **SETUP** screen.

### C.O. Fast Mode

When the **C.O. MODE** is set to **FAST**, the monitor will display the unfiltered C.O. value (CO-f) rather than the averaged value. The text **FAST MODE** will replace the CObar graphic. The stroke volume and cardiac index will be calculated from this value rather than the averaged value.

The averaged C.O. value can still be viewed as **CO-a** under the VCO<sub>2</sub> value in the **LAST COMPLETED CYCLE** screen.

The **C.O. MODE** option is set in the **SETUP** screen.





# Respiratory Monitoring

This section details the steps needed to begin patient respiratory mechanics monitoring with the NICO® monitor.

## Preparing for Use

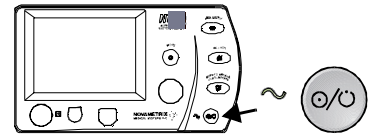
### Inspect

Before monitoring, take a few moments to inspect the NICO® monitor and its sensors. Check that all items are clean, dry, and physically intact with no broken or damaged components.

### Turn on the monitor

Turn the NICO® monitor on.

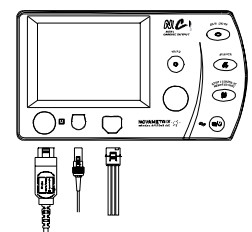
- 1 Press the **Operate/Standby** key to turn the monitor on and off.
  - NICO® can operate from its internal battery or from the AC Mains. (See “AC/Battery Operation” on page 4 for details.)
- 2 The monitor performs a quick self-test.
  - An audible tone sounds, the key indicators illuminate, and a **SELF-TEST IN PROGRESS** message is briefly displayed.
- 3 The message **PRESS KNOB TO ERASE STORED TRENDS** is displayed for 5 seconds.
  - To erase the contents of the monitor's trend memory, press the knob. **TRENDS ERASED** is briefly displayed.
  - To retain the contents of the monitor's trend memory, do not press the knob. Wait the 5 seconds and **TRENDS RETAINED** is displayed.
  - Note: If the internal battery becomes fully discharged, the message **CHECK DATE/TIME (MENU -> SETUP)** will appear before the **PRESS KNOB TO ERASE STORED TRENDS** message. (See “Setup Screen” on page 45 for details.)
- 4 The power up sequence is completed and a monitoring screen is displayed.
  - NICO® displays the screen that was displayed when the monitor was last turned off.
  - If the monitor is in Cardiac Output mode, connecting a CO<sub>2</sub>/Flow sensor will cause the monitor to automatically switch to Respiratory Mechanics mode.
  - The monitor is in a READY state and the parameters will be dashed and alerts will not be active until parameters are calculated and displayed.
  - Parameters will display and their alerts will become active as they are calculated.



### Connect and apply the sensors

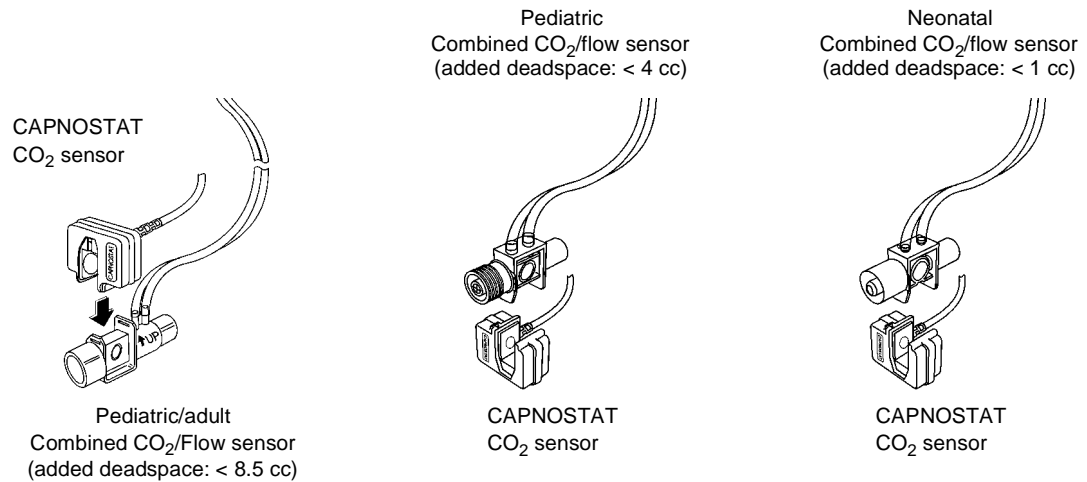
Connect the sensors to the monitor, ventilator circuit, and patient.

- 1 Connect the SpO<sub>2</sub> sensor to the monitor and apply it to the patient. (See “Pulse Oximetry Sensors” on page 67.)
- 2 Connect the CAPNOSTAT® CO<sub>2</sub> Sensor to the monitor. (See “CAPNOSTAT® CO<sub>2</sub> Sensor” on page 65.)
- 3 Select an appropriate size CO<sub>2</sub>/Flow sensor.
- 4 Connect a CO<sub>2</sub>/Flow Sensor to the monitor and attach a CAPNOSTAT®. (See “CO<sub>2</sub>/Flow Sensors” on page 62.)

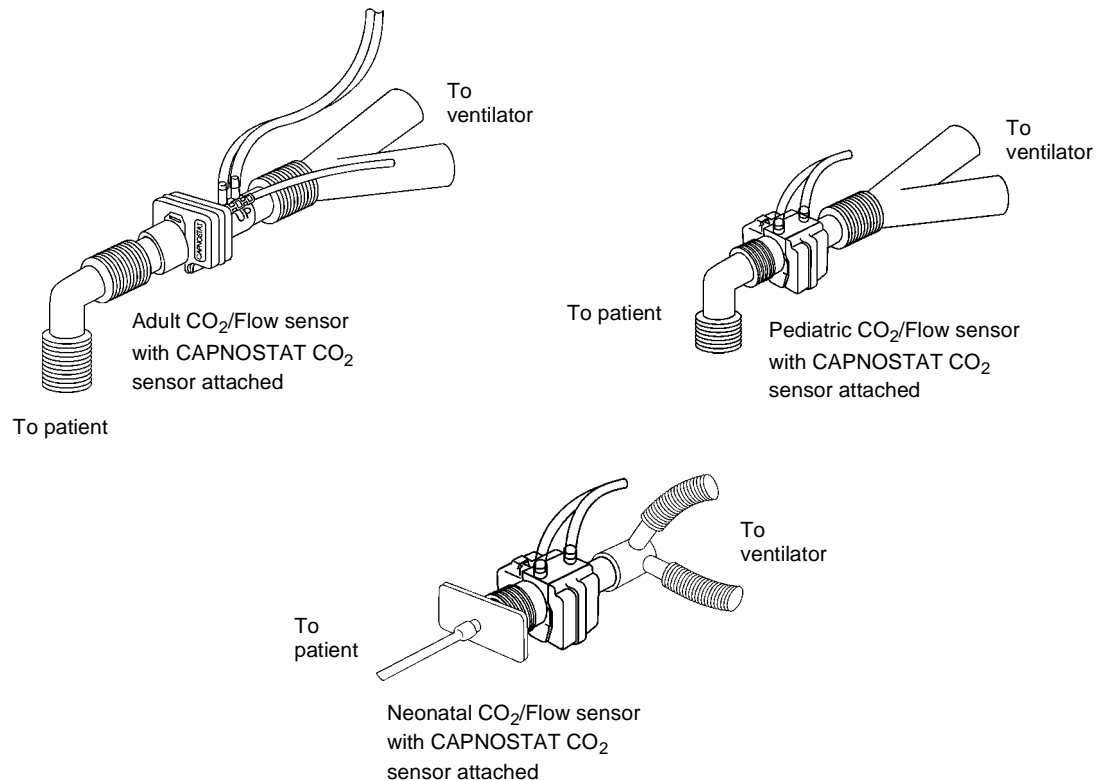




- 5 Connect the CAPNOSTAT CO<sub>2</sub> sensor to the CO<sub>2</sub>/Flow sensor.



- 6 For optimal results, place the CO<sub>2</sub>/Flow sensor in the ventilator circuit between the endotracheal tube and the ventilator circuit wye.
- Place the sensor proximal to the patient if using other devices in the circuit.
  - Place the sensor so that the tubing lines exit from the top of the sensor (to help keep them clear and dry).
  - Keep the sensor clear of accumulations by proper circuit maintenance.
- 7 Connect the combined CO<sub>2</sub>/Flow sensor to the patient breathing circuit.

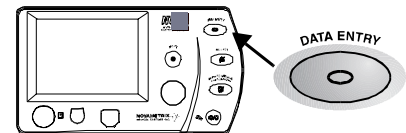


- Do NOT place the CO<sub>2</sub>/Flow sensor between the ET tube and the elbow (pediatric/adult circuit), as this may allow patient secretions to block the adapter windows.
- Position the CO<sub>2</sub>/Flow sensor with its windows in a vertical and NOT a horizontal position: this helps keep patient secretions from “pooling” on the windows.
- To prevent “rain-out” and moisture from draining into the CO<sub>2</sub>/Flow sensor, do NOT place the CO<sub>2</sub>/Flow sensor in a gravity dependent position.
- Periodically check the CO<sub>2</sub>/Flow sensor and tubing for excessive moisture or secretion build up.
- For routine performance of airway care, separate the system between the ET tube and the airway adapter (neonatal circuit), or between the ET tube and elbow (pediatric/adult circuit). Lavage and suctioning of the airway can then be performed without fluids and mucous accumulating on the CO<sub>2</sub>/Flow sensor windows.

## Begin Respiratory Monitoring

After the NICO® monitor is turned on and the sensors are properly connected and applied, Respiratory Mechanics monitoring can begin.

- 1 Enter the delivered oxygen and balance gas or anesthetic agent if present, by pressing the **DATA ENTRY** key. (See “Entering Patient Data” on page 34.)
- 2 As you begin monitoring with NICO®, please note the following:



- Water that accumulates in the CO<sub>2</sub>/Flow sensor or the sensor tubing may cause the reported Tidal Volumes to be higher than set volumes. If reported values are higher (or lower) than expected and water is seen in the line or sensor body, purge the lines. If purging does not clear the water, remove the sensor from the circuit and remove the water by shaking the sensor, or by flowing oxygen or compressed air through the tubing or sensor until the water is removed. Do not use high pressure for water removal.
- To minimize the effects of aerosolized medications on the CO<sub>2</sub>/Flow sensor, it is recommended that the CO<sub>2</sub>/Flow sensor be removed from the ventilator circuit prior to the delivery of the medication. ***The decision to remove or not remove the CO<sub>2</sub>/Flow sensor is the responsibility of the clinician.***
- During the purge cycle the pump will be heard.
- Water will condense in the pressure sense lines at a faster rate when used in cooler ambient temperatures.
- Always keep the CO<sub>2</sub>/Flow sensor tubing pointed in an upward position to minimize pooling of water and secretions at the pressure sense line openings.
- The automatic purge mode may not be disabled.
- During a very low battery condition, automatic and manual purging is not allowed.

## Entering Patient Data

Respiratory monitoring can be enhanced by the entry of key patient specific data including respired gas composition (anesthetic agent, balance gas, and inspired O<sub>2</sub>).

Patient data should be updated in the **DATA ENTRY** screen whenever possible. The screen may be accessed at any time by pressing the **DATA ENTRY** key.

**DATA ENTRY settings** The following table lists the parameters and ranges accessible in the **DATA ENTRY** screens.

Label	Parameter	Default	Range/Units	Description
INSP O <sub>2</sub>	Inspired Oxygen	70%	21-100 %	Percent of oxygen in the inspired gas. Must be entered in order for NICO® to accurately calculate parameters.
INSP AGENT	Inspired Anesthetic Agent	0%	0-20 %	Percent of anesthetic agent in the inspired gas. Must enter percent delivered in order for NICO® to accurately calculate parameters.
BALANCE	Gas Balance	N <sub>2</sub>	N <sub>2</sub> , He, or N <sub>2</sub> O	N <sub>2</sub> , He, or N <sub>2</sub> O. Must select the correct balance in the inspired gas in order for NICO® to accurately calculate parameters.
HEIGHT	Patient Height	--	35-91 in 90-230 cm	Enter patient height.
WEIGHT	Patient Weight	--	Neonatal: 0.22 - 44.09 lb 0.10 - 20.00 kg  Pediatric: 0.2 - 220.2 lb 0.1 - 99.9 kg  Adult: 55-551 lb 25-250 kg	Enter patient weight for respiratory mechanics calculations.
<b>ABG DATA ENTRY Screen</b>				
PaCO <sub>2</sub>	Arterial Carbon Dioxide	40 mmHg (5.4 kPa or %)  ("--" displayed until an initial value is entered)	0-250 mmHg 0.0-20.0 kPa 0.0-20.0 %	Partial pressure of carbon dioxide in arterial blood. Enter this value for calculation of Vd alv (alveolar deadspace), Vd/Vt (deadspace to tidal volume ratio) and Vd phys (physiologic deadspace).
PaO <sub>2</sub>	Arterial Oxygen	FiO <sub>2</sub> (Pb-47 mmHg) ("--" displayed until an initial value is entered)	0-750 mmHg 0.0-99.5 kPa 0.0-99.5 %	Partial pressure of oxygen in arterial blood.  Enter a value for this parameter if desired; does not affect CO <sub>2</sub> /flow calculations.
Hb	Hemoglobin Concentration or Hematocrit	11.0 gm/dL 6.8 mmol/L 33 % ("--" displayed until an initial value is entered)	Hb: 5.0-20.0 gm/dL Hb: 3.1-12.4 mmol/L Hct: 0-60 %	Concentration of hemoglobin or hematocrit in the blood.  Enter a value for parameter if desired; does not affect CO <sub>2</sub> /flow calculations.
MARK ABG TIME	Time when ABG blood sample is drawn	Current Time	hh:mm (hours:minutes)	Enter time ABG is drawn. Only accepts time since ETCO <sub>2</sub> was first detected.
DEFAULT ABGs	Blood gas values	PaCO <sub>2</sub> : 5 mmHg (0.7kPa or %) above the measured ETCO <sub>2</sub> value <sup>a</sup>  PaO <sub>2</sub> : Based on barometric pressure and INSP O <sub>2</sub> value.  Hb: 11.0 gm/dL		Resets blood gas settings to default values.

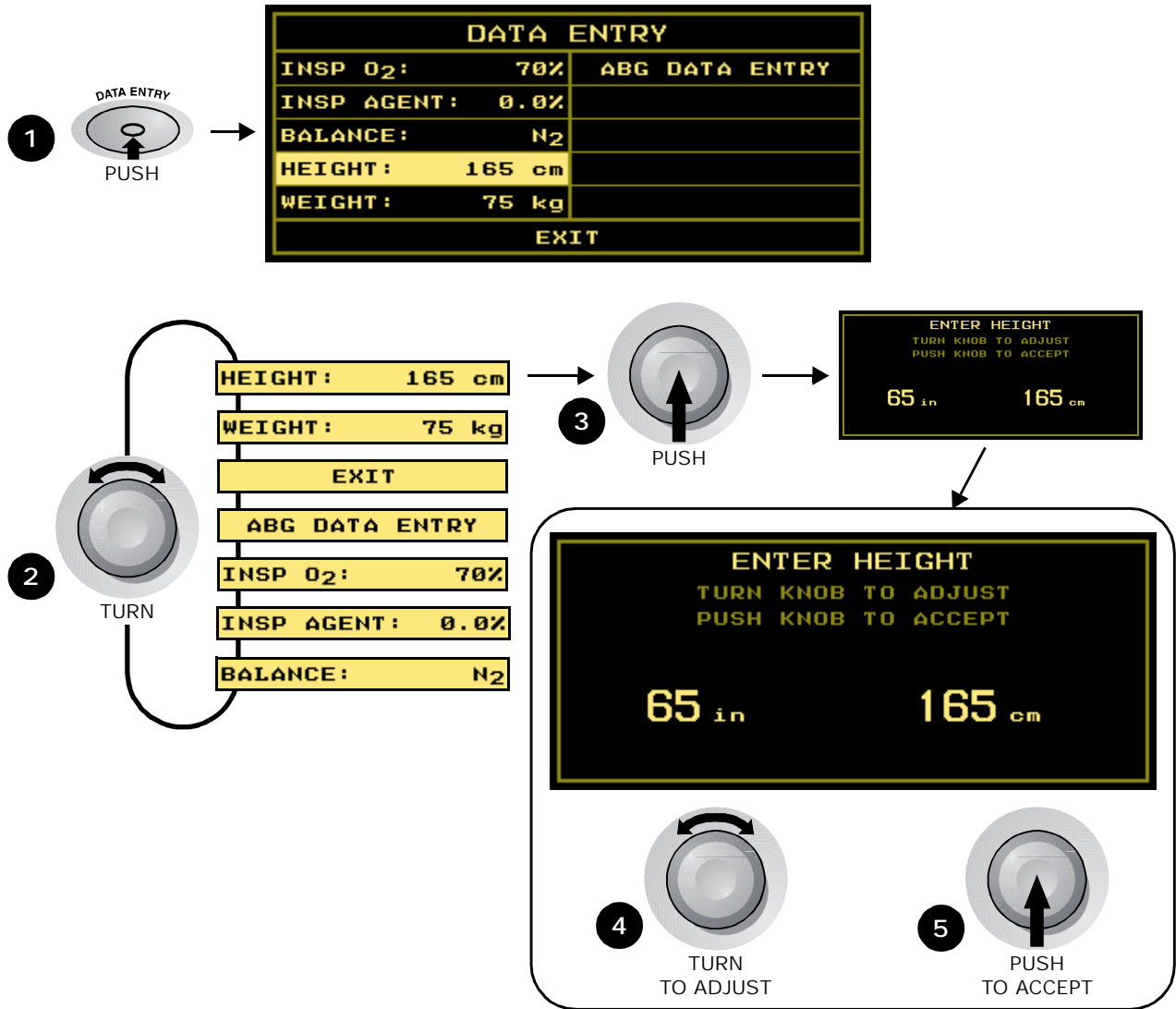
a. 40mmHg (5.4 kPa or %) if ETCO<sub>2</sub> is not available.

## Entering ABG Data

### Entering Patient Data

To enter (or view) patient data:

- 1 Press the **DATA ENTRY** key to activate **DATA ENTRY**. The key's green icon illuminates.
  - Press the key again to return to the previously displayed screen.
- 2 Highlight the desired data by turning the **KNOB**.
- 3 Select the highlighted data by pressing the **KNOB**.
- 4 Turn the **KNOB** to adjust the value as desired.
- 5 Press the **KNOB** to accept the value.
- 6 Repeat these steps for the other settings.



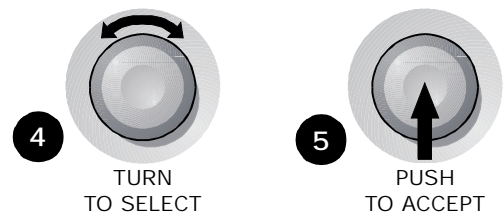
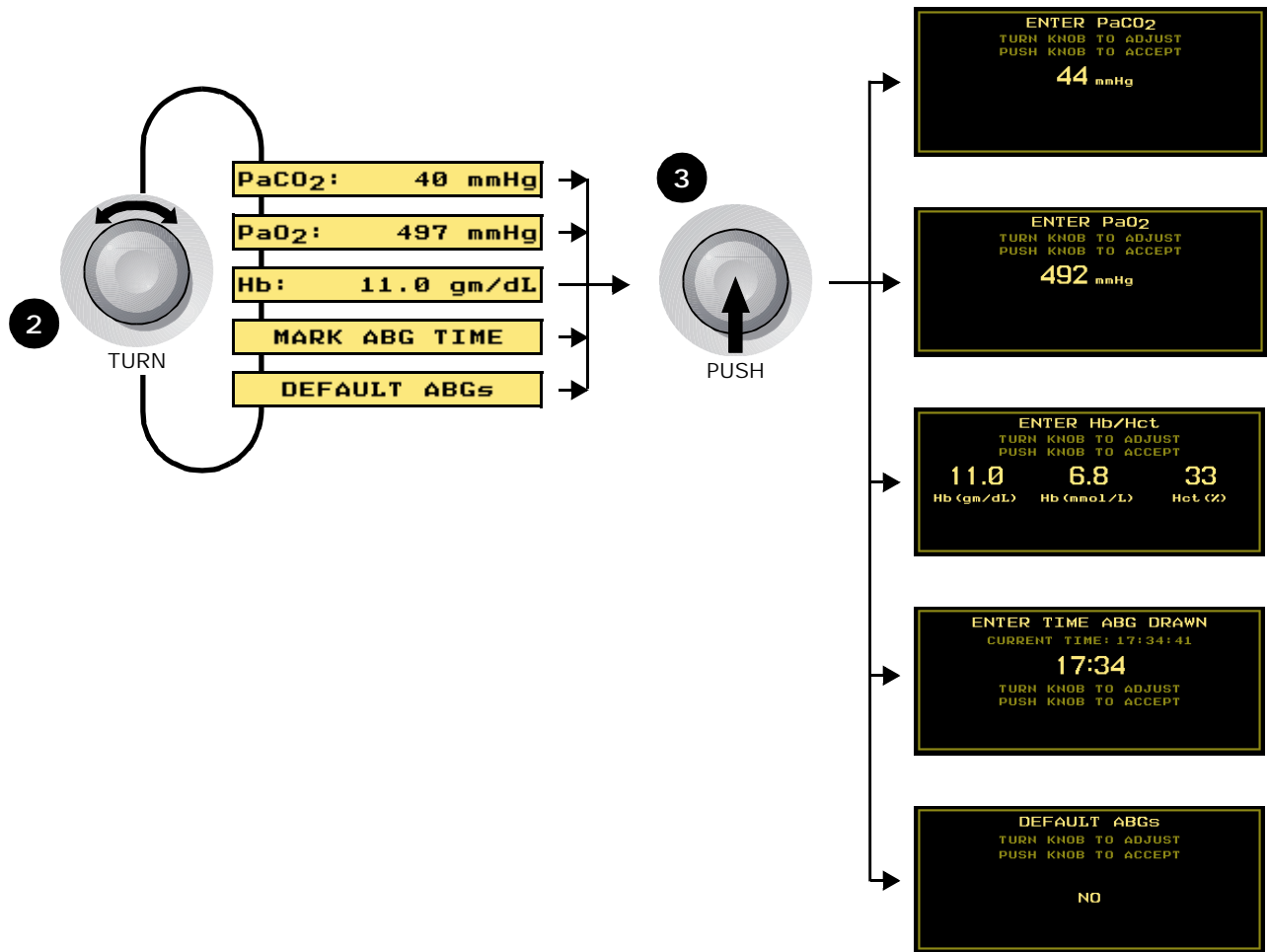
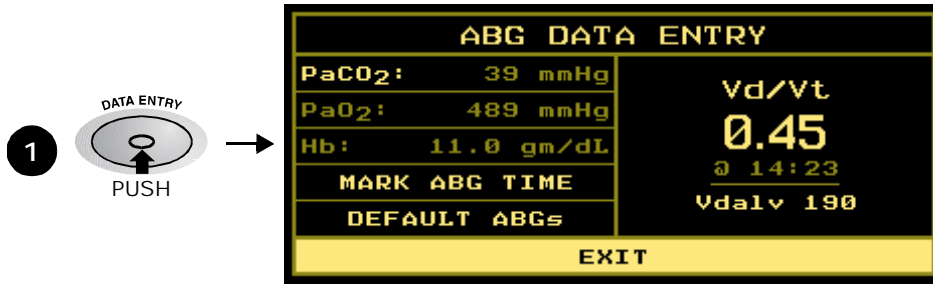
## Entering ABG Data

To enter ABG data:

- 1 Press the **DATA ENTRY** key to activate **DATA ENTRY**. The key's green icon illuminates.
  - Press the key again to return to the previously displayed screen.
- 2 Highlight **ABG DATA ENTRY** by turning the **KNOB**.

Entering ABG Data

- 3 Select **ABG DATA ENTRY** by pressing the **KNOB**.



- 4 Turn and press the **KNOB** to select the PaCO<sub>2</sub>, PaO<sub>2</sub>, Hb/Hct, Mark ABG Time or Default ABG screen.  
NOTE: PaO<sub>2</sub> and Hb selections are dimmed in Respiratory Mechanics mode to denote that, although they are available for data input, the data will not affect parameter calculations.
- 5 Turn **KNOB** to adjust value.
  - ABG Time is required for PaCO<sub>2</sub>.
  - Ensure that the NICO® clock is synchronized to the clock used to determine the draw time.
- 6 Press the **KNOB** to accept the value.
  - Updated Vd/Vt and Vd<sub>alv</sub> values are displayed.



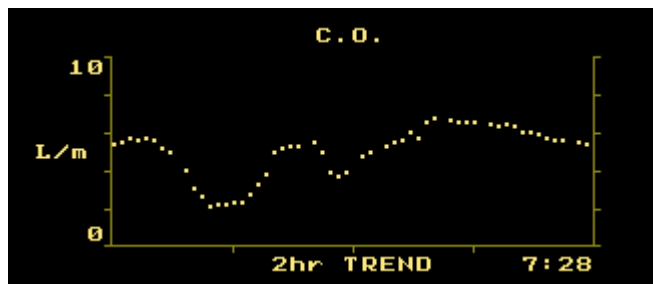
## Monitoring and Setup Screens

### Cardiac Output mode

This section provides an overview of monitoring and setup screens in Cardiac Output mode.

#### C.O. Trend Screen

The Cardiac Output Trend Screen plots cardiac output over time.

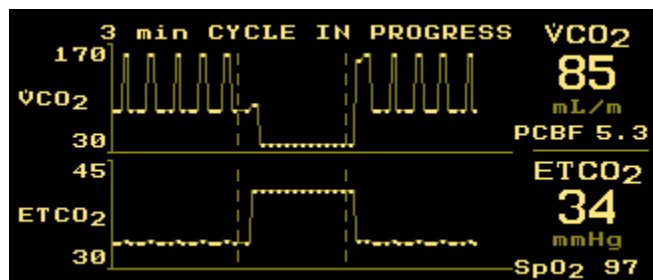


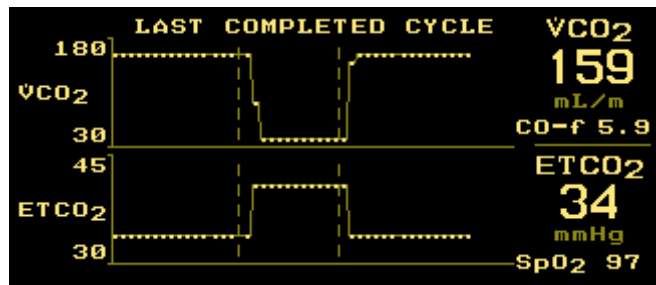
The **C.O. TREND** screen can be displayed by turning the **KNOB** while viewing any monitoring screen, or by pressing the **MENU** key and selecting **C.O. TREND**.

- While viewing the **C.O. TREND** screen, each push of the **KNOB** will advance through the available 2, 4, 8 and 12 hour trend displays.
- Data is plotted from left (oldest data) to right (newest data). Once the display is filled, data shifts left so that the oldest data point on the left is pushed out to make room for the newest point entering from the right.
- The current time is shown in the lower right corner of the display and represents time at the right edge of the screen. See "Setup Screen" on page 45 to set the time.
- Each point on the trend (plotted or blank) represents the average C.O. value over a time period. The time periods are: 1 minute average for the 2 hour trend, 2 minutes for the 4 hour trend, 4 minutes for the 8 hour trend, and 6 minutes for the 12 hour trend.
- C.O. trends are automatically scaled to fit 0-5, 0-10, 0-15 and 0-20 L/min scales.
- A two-pixel wide dashed vertical line in the trend is used to denote a power-cycle where the NICO® monitor was turned off and back on.

#### Rebreathing Curves Screens

There are two Rebreathing Curves Screens—one displays the last completed NICO® cycle, and the other shows the current cycle. Both plot  $\text{VCO}_2$  and  $\text{ETCO}_2$  values over time and also provide numeric displays for  $\text{VCO}_2$ ,  $\text{ETCO}_2$  and pulse rate. Additionally,  $\text{CO-f}$  (C.O. fast-mode, unaveraged) is reported for the last completed cycle.



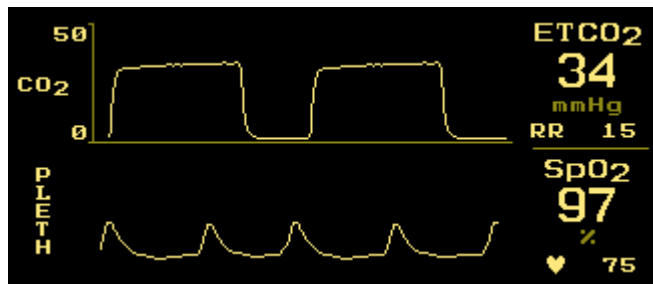


The Rebreathing Curves Screens can be displayed by turning the **KNOB** while viewing any monitoring screen, or by pressing the **MENU** key and selecting **REBREATH CURVES**. To switch between the two curves, push the **KNOB**.

- Data is plotted from left (oldest data) to right (newest data).
- Points on the trend (plotted or blank) represent the VCO<sub>2</sub> or ETCO<sub>2</sub> value for each breath.
- The curves are automatically scaled to fit the display area.
- Two one-pixel wide dashed vertical lines are used to divide the curve into its baseline, rebreathing and stabilization phases.
- ETCO<sub>2</sub> and SpO<sub>2</sub> values will flash if an alert limit is exceeded.

### CO<sub>2</sub> and SpO<sub>2</sub> Waveform Screen

The CO<sub>2</sub> and SpO<sub>2</sub> Waveform Screen plots the capnogram and plethysmogram signals as well as providing numeric displays of ETCO<sub>2</sub>, Respiratory rate, SpO<sub>2</sub> and pulse rate (♥).

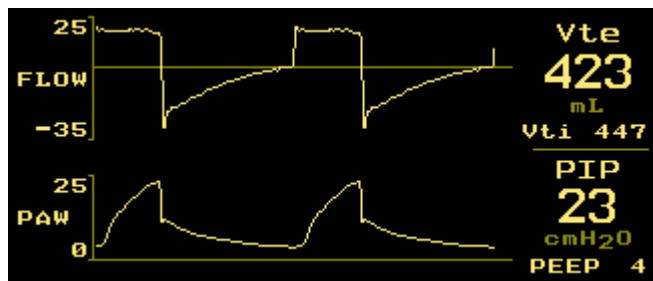


The CO<sub>2</sub>/SpO<sub>2</sub> screen can be displayed by turning the **KNOB** while viewing any monitoring screen, or by pressing the **MENU** key and selecting **CO<sub>2</sub>/SpO<sub>2</sub>**.

- Information is updated in real time and reflects current patient status.
- The capnogram and plethysmogram are automatically scaled.
- The capnogram sweep speed is selectable in the **SETUP** menu.
- ETCO<sub>2</sub>, RR, SpO<sub>2</sub> and pulse rate values will flash if an alert limit is exceeded.

### Flow and Pressure Waveform Screen

The Flow and Pressure Waveform screen plots the airway flow and pressure signals over time as well as providing numeric displays of Vte, Vti, PIP and PEEP.





*Respiratory Screens (Optional)*

The **FLOW/PRESSURE** screen can be displayed by turning the **KNOB** while viewing any monitoring screen, or by pressing the **MENU** key and selecting **FLOW/PRESSURE**.

- Information is updated in real time.
- The airway flow and pressure waveforms are automatically scaled.
- The waveform sweep speed is selectable in the **SETUP** menu.

**Numerics Screen**

The **NUMERICS** screen display presents several monitored parameters together in one place.

ETCO <sub>2</sub> 34 mmHg RR 15	SpO <sub>2</sub> 97 % ♥ 75	MValv 5.2 L MV 6.2	PIP 23 cmH <sub>2</sub> O MAP 9
VCO <sub>2</sub> 81 mL/m	Cdyn 27 mL/cmH <sub>2</sub> O	Raw 15 cm/(L/s)	PEEP 4 cmH <sub>2</sub> O

The **NUMERICS** screen can be displayed by turning the **KNOB** while viewing any monitoring screen, or by pressing the **MENU** key and selecting **NUMERICS**.

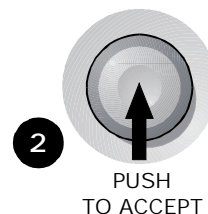
- Information is updated in real time.
- The PEEP label is replaced with AUTO if Auto-PEEP (Intrinsic-PEEP) is detected.
- ETCO<sub>2</sub>, RR, SpO<sub>2</sub> and pulse rate values will flash if an alert limit is exceeded.

**Respiratory Screens (Optional)**

NICO® offers four optional respiratory screens, displaying Respiratory Numerics, Flow Volume and Pressure Volume Loops, a Single Breath CO<sub>2</sub> Waveform, and the VCO<sub>2</sub>/MValv Trend. Press the **MENU** key and select **RESP SCREENS** from the **SELECT A SCREEN** menu by turning and then pressing the **KNOB**.

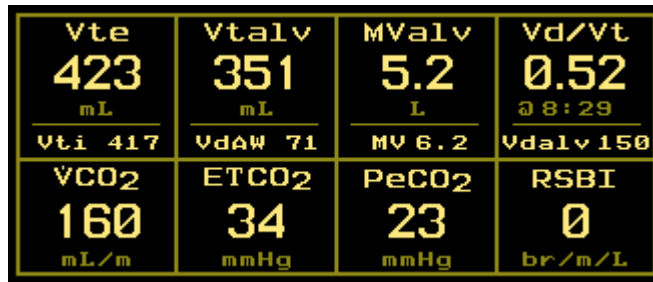
From the **ADD RESPIRATORY SCREENS** menu, highlight and then select which screens will appear in the base monitoring mode by turning and then pressing the **KNOB**; screen choices are dimmed until selected. When enabled, selected screens can be displayed by turning the **KNOB** while viewing any monitoring screen (See "KNOB Selectable Respiratory Screens" on page 12).

ADD RESPIRATORY SCREENS	
RESP NUMERICS	SELECTED RESPIRATORY SCREENS CAN BE ACCESSED BY KNOB
FLOW/PRES/VOL	
SINGLE BREATH CO <sub>2</sub>	
VCO <sub>2</sub> /MV <sub>alv</sub> TREND	
EXIT	



## Respiratory Screens (Optional)

**Respiratory Numerics** The **RESPIRATORY NUMERICS** screen presents several monitored parameters together in one place.

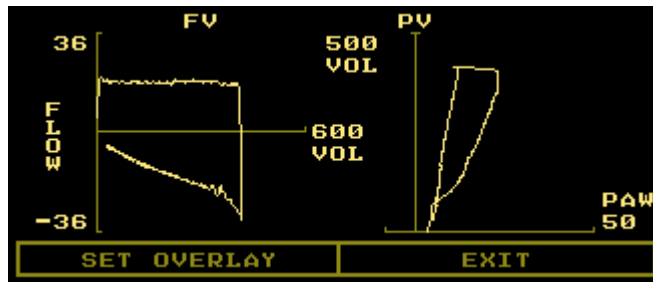


The **RESPIRATORY NUMERICS** screen can be displayed, when enabled, by turning the **KNOB** while viewing any monitoring screen.

- Information is updated in real time.
- ETCO<sub>2</sub> value will flash if an alert limit is exceeded.

## Flow Volume and Pressure Volume Loops

The Flow Volume and Pressure Volume Loops screen displays a flow versus volume loop and a volume versus peak airway pressure loop.

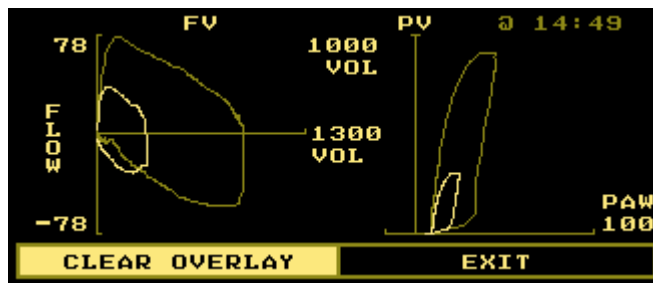


The Flow Volume and Pressure Volume Loops screen can be displayed, when enabled, by turning the **KNOB** while viewing any monitoring screen.

- The flow-volume loop is plotted in a clockwise direction, comparing flow versus volume for a single patient breath and providing information regarding the condition of the airways.
- The pressure-volume loop is plotted in a counter-clockwise direction; the slope from the beginning of inspiration to the end of inspiration depicts compliance while the width of the loop references resistance.
- The curve is automatically scaled to fit the display area.

## Set Overlay

The Set Overlay function “freezes” a single breath on the **FLOW/PRES/VOL** screen as a template. Subsequent loops will be drawn over that breath.



- Press the **KNOB** to highlight **SET OVERLAY** and again to select the breath.
- Press the **KNOB** to highlight **CLEAR OVERLAY** and again to erase the selected breath.
- The time stamp above the template wave corresponds to when the overlay was set.

## Single Breath CO<sub>2</sub>

The **SINGLE BREATH CO<sub>2</sub>** screen displays the CO<sub>2</sub> waveform for a single patient breath, as well as providing numeric displays of VCO<sub>2</sub>, Vte, ETCO<sub>2</sub>, Vtalv, Vti, and VdAw.



SBCO<sub>2</sub> presents the exhaled concentration of CO<sub>2</sub> versus tidal volume during a single expiration; useful for understanding the ventilation/perfusion relationship. It allows the clinician to detect relative changes in CO<sub>2</sub> production, deadspace, and effective ventilation by observing the shape of the graph.

- The curve is automatically scaled to fit the display area.

## Set Overlay

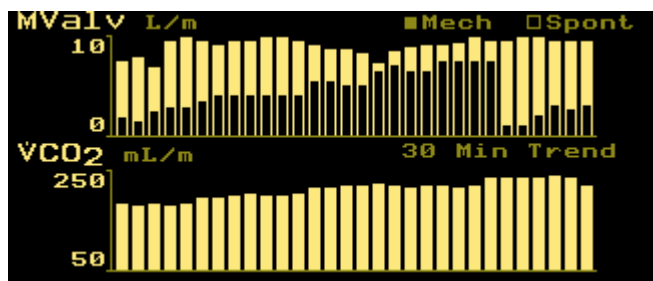
The Set Overlay function “freezes” a breath on the **SINGLE BREATH CO<sub>2</sub>** screen as a template. Subsequent waveforms will be drawn over that breath for comparison.



- Press the **KNOB** to highlight **SET OVERLAY** and again to select the breath.
- Press the **KNOB** to highlight **CLEAR OVERLAY** and again to erase the selected breath.
- The time stamp above the template wave corresponds to when the overlay was set.

## VCO<sub>2</sub>/MValv Trend

The **VCO<sub>2</sub>/MVALV TREND** screen displays trends for alveolar minute ventilation and CO<sub>2</sub> elimination. Monitoring spontaneous versus mechanical alveolar ventilation along with CO<sub>2</sub> elimination provides information on continued success or impending failure when weaning a patient off a ventilator.



- While viewing the **VCO<sub>2</sub>/MV ALV TREND** screen, each push of the knob will advance through the available 30 minute, and 2, 4, 8, and 12 hour trend displays.
- Data is plotted from left (oldest data) to right (newest data). Once the display is filled, data shifts left so that the oldest data point on the left is pushed out to make room for the newest point entering from the right.

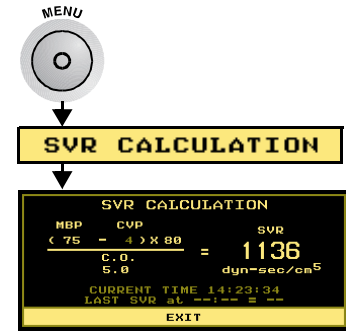
- Each bar on the trend represents the average MValv or VCO<sub>2</sub> value over a time period. The time periods are: 1 minute average for the 30 minute trend, 4 minute average for the 2 hour trend, 8 minutes for the 4 hour trend, 16 minutes for the 8 hour trend, and 24 minutes for the 12 hour trend.

### Systemic Vascular Resistance (SVR) Calculation

The **SVR CALCULATION** screen displays the Systemic Vascular Resistance formula and allows for entering the MBP, CVP and C.O. values for calculating the SVR value. The screen also displays the current time and last SVR value.

To calculate the SVR value:

- Press the **MENU** key. The **SELECT A SCREEN** menu appears.
- Highlight and then select **SVR CALCULATION** by turning and then pressing the knob.
- The **SVR CALCULATION** screen is displayed.
- Press then turn the **KNOB** to adjust the setting.
  - MBP** - Mean Blood Pressure (25 to 300 mmHg).
  - CVP** - Central Venous Pressure (-9 to 25 mmHg).
  - C.O.** - Cardiac Output (0.5 to 19.9 L/m). This value will correspond to the displayed value (**AVERAGED** or **FAST**) and its value can be manually changed. If manually changed, the value will not be updated to reflect the displayed value.
  - SVR** - Systemic Vascular Resistance (0 to 5000 dynes sec/cm<sup>5</sup>). Appears as "----" until the **MBP** value is entered.
  - 80** - A constant factor used to convert from Wood to VRU units.
- Press the **KNOB** to accept the displayed value; turn to select the next setting.



$$\frac{(\text{MBP} - \text{CVP}) \times 80}{\text{C.O.}} = \text{SVR} \text{ dyn-sec/cm}^5$$

### Tabular Data Screen

The **TABULAR DATA** screen displays the data collected for all NICO® parameters, in three-minute increments, in a table format.

The parameter displayed in each column will vary, depending on the setting chosen by the user.

- Highlight and select the desired column by turning then pressing the **KNOB**.
- Turn the **KNOB** to advance through all available NICO® parameters.
- Press the **KNOB** to accept the displayed parameter; turn to select the next column.

TIME	CO-a	CI	SpO <sub>2</sub>	ETCO <sub>2</sub>	VCO <sub>2</sub>
11:40	6.1	2.4	97	35	156
11:43	5.7	2.3	97	35	156
11:46	5.7	2.3	97	35	156
11:47	5.3	2.1	97	39	74
11:48	6.1	2.1	97	34	157
11:52	5.7	2.3	97	35	156
11:55	5.7	2.3	97	35	156
EXIT					

### Time Column

With the **TIME** column selected (flashing), turn the **KNOB** to display NICO® parameters collected since the beginning of the monitoring session; the most recent records are at the bottom of the table. Three arrows ↓↓↓ will display at the bottom of the column when more records are available.

## Set Alerts Screen

The **SET ALERTS** screen displays the current patient values as well as the LOW and HIGH alert limit settings for various parameters. This screen also allows adjustment of alert limits, audible alert volume, and of the “No Respiration” alert. See “Alerts” on page 56 for details.

SET ALERTS	CURRENT	LOW	HIGH
CO (L/m)	6.5	OFF	OFF
ETCO <sub>2</sub> (mmHg)	34	OFF	OFF
SpO <sub>2</sub> (%)	97	OFF	OFF
RR (br/m)	15	OFF	OFF
♥ (bpm)	75	OFF	OFF
AUDIO: 10		NO RESP: 20s	
AUTO LIMITS		EXIT	

The **SET ALERTS** screen can only be displayed by pressing the **MENU** key and selecting **SET ALERTS**.

- **CURRENT** - the current patient value for a parameter, shown in real time  
NOTE: The **CURRENT** value will flash when a high or low alert limit is exceeded.
- **LOW** and **HIGH** - the values below and above which an alert will be generated
- (Bell with slash) - the audible alert is disabled for this limit
- (Bell) - the audible alert is enabled for this limit
- **AUDIO** - set the audible alert volume level
- **AUTO LIMITS** - have the NICO® monitor bracket alerts around current patient values
- **NO RESP** - set the No Respiration alert delay timer

## Setup Screen

The **SETUP** screen allows the user to perform certain functions, such as a CO<sub>2</sub> Zero, erase trend data, change items like the waveform trace sweep speed and to set the time and date. Once set, the NICO® monitor will use these settings until again changed by the user.

To display the **SETUP** screen:

- 1 Press the **MENU** key to activate **SELECT A SCREEN**. The key's green icon illuminates.
  - Press the key again to return to the previously displayed screen.
- 2 Highlight and then select **SETUP** by turning and then pressing the **KNOB**.
- 3 The **SETUP** screen is displayed.
- 4 Again, turn the **KNOB** to highlight an item and push the **KNOB** to select it.



SETUP	
CO <sub>2</sub> ZERO NOW	PULSE BEEP: OFF
PURGE NOW	SWEEP: MEDIUM
IABP MODE: OFF	C.O. MODE: AVERAGE
ERASE TRENDS	SET SPON THRESH
INPUT/OUTPUT	SET TIME & DATE
EXIT	

Items within the **SETUP** screen are described below:

Label	Settings/Range	Description
CO <sub>2</sub> ZERO NOW	Start or Cancel (default: Start)	Displays the <b>CO<sub>2</sub> ZERO NOW</b> screen. Place the CAPNOSTAT® CO <sub>2</sub> Sensor onto a clean and dry adapter. Place the adapter in room air and away from all sources of CO <sub>2</sub> . Select <b>START</b> to begin a CO <sub>2</sub> Zero or <b>CANCEL</b> to exit the selection and return to the <b>SETUP</b> menu.
PURGE NOW	n/a	The system immediately purges the NICO Sensor™ tubing. No messages are displayed. The Purge takes approximately 8 seconds. The flow and pressure waveform traces will return to zero during this period.

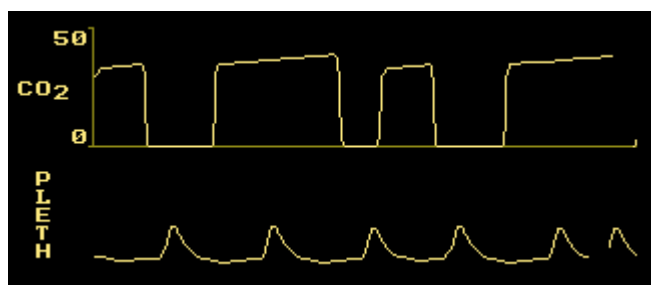
Label	Settings/Range	Description
IABP Intra-Aorta Balloon Pump	ON or OFF	Displays the <b>SET SpO<sub>2</sub> IABP MODE</b> screen. Turn the <b>KNOB</b> to select <b>OFF</b> (default setting) or <b>ON</b> to turn off the validator algorithm so that all pulsatile data, including the normally rejected artifact generated by the IABP, are allowed to influence the SpO <sub>2</sub> and Pulse Rate calculations. Push the <b>KNOB</b> to accept your selection and return to the <b>SETUP</b> menu.
ERASE TRENDS	Yes or No (default: No)	Displays the <b>ERASE STORED TRENDS?</b> screen. Turn the <b>KNOB</b> to select <b>NO</b> (the default setting) or <b>YES</b> . Push the <b>KNOB</b> to accept your selection and return to the <b>SETUP</b> menu.
INPUT/OUTPUT	ANALOG OUT 1-4 ANALOG CAL. RS232-2/RS232-3	Turn the <b>KNOB</b> to select <b>ANALOG OUT 1</b> through <b>ANALOG OUT 4</b> , <b>ANALOG CAL.</b> , <b>RS232-2</b> or <b>RS232-3</b> . Push the <b>KNOB</b> to accept your selection and assign it the desired output parameter.
PULSE BEEP	OFF and 1-10 (default: OFF)	Displays the <b>SET PULSE BEEP</b> screen. Turn the <b>KNOB</b> to select a volume (1-10 and OFF) for the audible tone to accompany each detected pulse beat. Push the <b>KNOB</b> to accept your selection and return to the <b>SETUP</b> menu.
SWEEP	Slow, Medium, Fast (default: Medium)	Displays the <b>SET SWEEP SPEED</b> screen. Turn the <b>KNOB</b> to select how quickly the CO <sub>2</sub> , Flow and Pressure waveforms sweep across the display (Plethysmogram is unaffected). Push the <b>KNOB</b> to accept your selection and return to the <b>SETUP</b> menu.
C.O. MODE	AVERAGE or FAST	Displays the <b>SET C.O. MODE</b> screen. Turn the <b>KNOB</b> to select <b>AVERAGE</b> (CO-a, CObar displayed), <b>FAST</b> (CO-f, CObar not displayed). Push the <b>KNOB</b> to accept your selection and return to the <b>SETUP</b> menu.
SET SPON THRESHOLD	0-50 cmH <sub>2</sub> O	Displays the <b>SET SPONTANEOUS THRESHOLD</b> screen. The spontaneous threshold is the airway pressure chosen to differentiate between a spontaneous (patient-initiated) breath and a mechanical (ventilator) breath. Turn the <b>KNOB</b> to adjust the setting indicated by a dashed line. For optimal setting of the spontaneous threshold, the dashed line should be above any spontaneous breaths and below the mechanical breaths. Push the <b>KNOB</b> to accept your selection and return to the <b>SETUP</b> menu.
SET TIME & DATE	hh:mm dd mmm yyyy	Displays the <b>SET TIME / DATE</b> screen. Turn the <b>KNOB</b> to highlight the portion of the time/date to change. Push the <b>KNOB</b> to select that item—it begins to flash. Turn the <b>KNOB</b> to adjust the flashing item, and when correctly set, push the <b>KNOB</b> again to accept the value. Repeat for the other time/date entries. Finally, turn the <b>KNOB</b> to highlight <b>EXIT</b> and push the <b>KNOB</b> to return to the <b>SETUP</b> menu.

## Respiratory Mechanics mode

This section provides an overview of the various monitoring and setup screens in Respiratory Mechanics mode.

### CO<sub>2</sub> and SpO<sub>2</sub> Waveform Screen

The CO<sub>2</sub> and SpO<sub>2</sub> Waveform Screen plots the capnogram and plethysmogram signals.

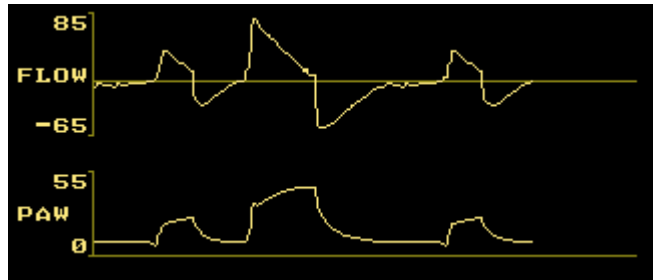


The  $\text{CO}_2/\text{SpO}_2$  screen can be displayed by turning the **KNOB** while viewing any monitoring screen, or by pressing the **MENU** key and selecting  $\text{CO}_2/\text{SpO}_2$ .

- Information is updated in real time.
- The capnogram and plethysmogram are automatically scaled.
- The capnogram sweep speed is selectable in the **SETUP** menu.

### Flow and Pressure Waveform Screen

The Flow and Pressure Waveform screen plots the airway flow and pressure signals over time.

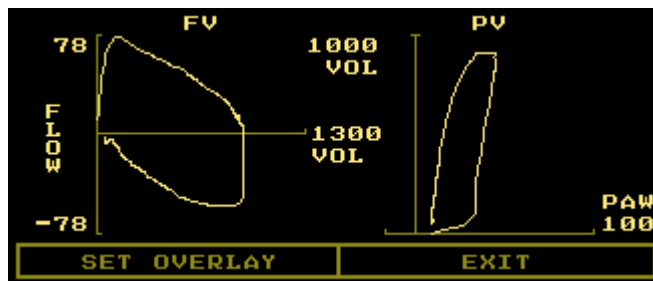


The **FLOW/PRESSURE** screen can be displayed by turning the **KNOB** while viewing any monitoring screen, or by pressing the **MENU** key and selecting **FLOW/PRESSURE**.

- Information is updated in real time.
- The airway flow and pressure waveforms are automatically scaled.
- The waveform sweep speed is selectable in the **SETUP** menu.

### Flow Volume and Pressure Volume Loops screen

The Flow Volume and Pressure Volume Loops screen displays a flow versus volume loop and a volume versus peak airway pressure loop.

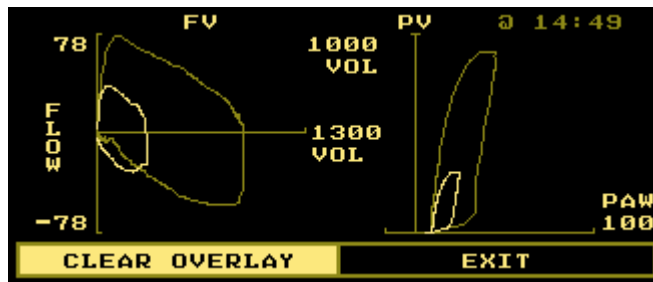


The **FLOW/PRES/VOL** screen can be displayed by turning the **KNOB** while viewing any monitoring screen, or by pressing the **MENU** key and selecting **FLOW/PRES/VOL**.

- The flow-volume loop is plotted in a clockwise direction, comparing flow versus volume for a single patient breath and providing information regarding the condition of the airways.
- The pressure-volume loop is plotted in a counter-clockwise direction; the slope from the beginning of inspiration to the end of inspiration depicts compliance while the width of the loop references resistance.
- The curve is automatically scaled to fit the display area.

### Set Overlay

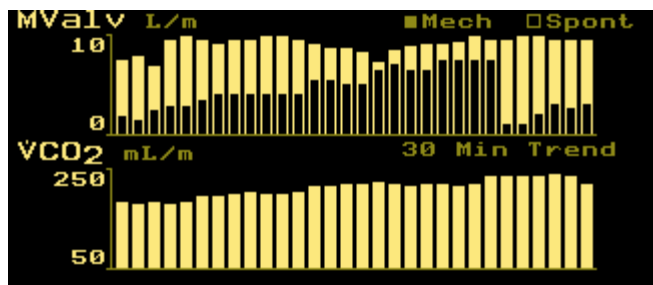
The Set Overlay function “freezes” a single breath on the **FLOW/PRES/VOL** screen as a template. Subsequent loops will be drawn over that breath.



- Press the **Knob** to highlight **SET OVERLAY** and again to select the breath.
- Press the **Knob** to highlight **CLEAR OVERLAY** and again to erase the selected breath.
- The time stamp above the template waveform corresponds to when the overlay was set.

### VCO<sub>2</sub>/MValv Trend Screen

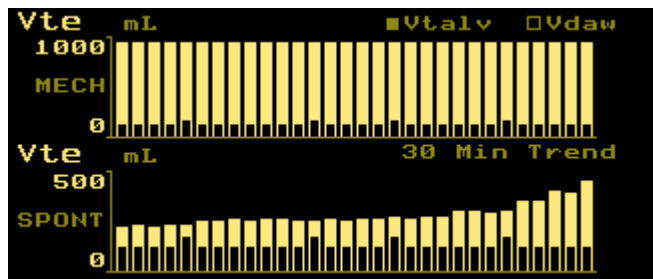
The **VCO<sub>2</sub>/MVALV** Trend screen displays trends for alveolar minute ventilation and CO<sub>2</sub> elimination. Monitoring spontaneous versus mechanical alveolar ventilation along with CO<sub>2</sub> elimination provides information on continued success or impending failure when weaning a patient off a ventilator.



- While viewing the **VCO<sub>2</sub>/MVALV** Trend screen, each push of the knob will advance through the available 30 minute, and 2, 4, 8, and 12 hour trend displays.
- Data is plotted from left (oldest data) to right (newest data). Once the display is filled, data shifts left so that the oldest data point on the left is pushed out to make room for the newest point entering from the right.
- Each bar on the trend represents the average MValv or VCO<sub>2</sub> value over a time period. The time periods are: 1 minute average for the 30 minute trend, 4 minute average for the 2 hour trend, 8 minutes for the 4 hour trend, 16 minutes for the 8 hour trend, and 24 minutes for the 12 hour trend.

### Vt/Vd Trend Screen

The **Vt/Vd TREND** screen displays trends for mechanical and spontaneous airway deadspace and alveolar tidal volume. Monitoring spontaneous versus mechanical deadspace along with expired tidal volume provides information on continued success or impending failure when weaning a patient off a ventilator.





- While viewing the **Vt/Vd TREND** screen, each push of the knob will advance through the available 30 minute, and 2, 4, 8, and 12 hour trend displays.
- Data is plotted from left (oldest data) to right (newest data). Once the display is filled, data shifts left so that the oldest data point on the left is pushed out to make room for the newest point entering from the right.
- Each bar on the trend represents the average Vtalv or Vdaw value over a time period. The time periods are: 1 minute average for the 30 minute trend, 4 minute average for the 2 hour trend, 8 minutes for the 4 hour trend, 16 minutes for the 8 hour trend, and 24 minutes for the 12 hour trend.

### Single Breath CO<sub>2</sub> Screen

The **SINGLE BREATH CO<sub>2</sub>** screen displays the CO<sub>2</sub> waveform for a single patient breath, as well as providing numeric displays of Vd/Vt, Vtalv, Vdaw, PeCO<sub>2</sub>, and Vdalv.



SBCO<sub>2</sub> presents the exhaled concentration of CO<sub>2</sub> versus tidal volume during a single expiration; useful for understanding the ventilation/perfusion relationship. It allows the clinician to detect relative changes in CO<sub>2</sub> production, deadspace, and effective ventilation by observing the shape of the graph.

- The curve is automatically scaled to fit the display area.

### Set Overlay

The Set Overlay function “freezes” a breath on the **SINGLE BREATH CO<sub>2</sub>** screen as a template. Subsequent waveforms will be drawn over that breath.



- Press the **Knob** to highlight **SET OVERLAY** and again to select the breath.
- Press the **Knob** to highlight **CLEAR OVERLAY** and again to erase the selected breath.
- The time stamp above the template wave corresponds to when the overlay was set.

### Numerics Screen

The **NUMERICS** screen display presents several monitored parameters together in one place.

Vd/Vt <b>0.20</b> 12:38	Vtalv <b>546</b> mL	MValv <b>11.0</b> L	PIP <b>26</b> cmH <sub>2</sub> O
Vdalv 58	VdAW 64	MAP 16	Pplat --
PeCO <sub>2</sub> <b>32</b> mmHg	Cdyn <b>21</b> mL/cmH <sub>2</sub> O	Raw <b>10</b> cm/(L/s)	PEEP <b>10</b> cmH <sub>2</sub> O

The **NUMERICS** screen can be displayed by turning the **KNOB** while viewing any monitoring screen, or by pressing the **MENU** key and selecting **NUMERICS**.

- Information is updated in real time.
- The PEEP label is replaced with AUTO if Auto-PEEP (Intrinsic-PEEP) is detected.

### Tabular Data Screen

The **TABULAR DATA** screen displays the data collected for all NICO® parameters, in one-minute increments, in a table format. Cardiac output-related parameters will not be displayed and will remain dashed (--) and inactive in Respiratory Mechanics mode.

The parameter displayed in each column will vary, depending on the setting chosen by the user.

- 1 Highlight and select the desired column by turning then pressing the **KNOB**.
- 2 Turn the **KNOB** to advance through all available NICO® parameters.
- 3 Press the **KNOB** to accept the displayed parameter; turn to select the next column.

TIME	PIP	CO-a	SpO <sub>2</sub>	ETCO <sub>2</sub>	VC0 <sub>2</sub>
11:12	32	--	97	39	430
11:13	32	--	97	39	430
11:14	32	--	97	39	430
11:15	32	--	97	39	430
11:16	32	--	97	39	430
11:17	32	--	97	39	430
11:18	30	--	97	39	430
EXIT					

### Time Column



With the **TIME** column selected (flashing), turn the **KNOB** to display NICO® parameters collected since the beginning of the monitoring session; the most recent records are at the bottom of the table. Three arrows ↓↓↓ will display at the bottom of the column when more records are available.

### Set Alerts Screen

The **SET ALERTS** screen displays the current patient values as well as the LOW and HIGH alert limit settings for various parameters (PIP is HIGH only). This screen also allows adjustment of alert limits, audible alert volume, and of the "No Respiration" alert. See "Alerts" on page 56 for details.

SET ALERTS	CURRENT	LOW	HIGH
PIP cmH <sub>2</sub> O	46		⚠ 120
ETCO <sub>2</sub> (mmHg)	39	⚠ 1	⚠ 150
SpO <sub>2</sub> (%)	97	⚠ 50	⚠ 100
RR (br/m)	20	⚠ 3	⚠ 150
♥ (bpm)	75	⚠ 31	⚠ 249
AUDIO: 4		⚠ NO RESP: 20s	
AUTO LIMITS		EXIT	

The **SET ALERTS** screen can only be displayed by pressing the **MENU** key and selecting **SET ALERTS**.

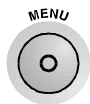
- **CURRENT** - the current patient value for a parameter, shown in real time  
NOTE: The **CURRENT** value will flash when a high or low alert limit is exceeded.
- **LOW** and **HIGH** - the values below and above which an alert will be generated
-  (Bell with slash) - the audible alert is disabled for this limit
-  (Bell) - the audible alert is enabled for this limit
- **AUDIO** - set the audible alert volume level
- **AUTO LIMITS** - have the NICO® monitor bracket alerts around current patient values
- **NO RESP:** - set the No Respiration alert delay timer

## Setup Screen

The **SETUP** screen allows the user to perform certain functions, such as a CO<sub>2</sub> Zero, erase trend data, change items like the waveform trace sweep speed and to set the time and date. Once set, the NICO® monitor will use these settings until again changed by the user.

To display the **SETUP** screen:

- 1 Press the **MENU** key to activate **SELECT A SCREEN**. The key's green icon illuminates.
  - Press the key again to return to the previously displayed screen.
- 2 Highlight and then select **SETUP** by turning and then pressing the **KNOB**.
- 3 The **SETUP** screen is displayed.
- 4 Again, turn the **KNOB** to highlight an item and push the **KNOB** to select it.



SETUP	
CO <sub>2</sub> ZERO NOW	PULSE BEEP: OFF
PURGE NOW	SWEEP: MEDIUM
IABP MODE: OFF	SET SPON THRESH
ERASE TRENDS	SET TIME & DATE
INPUT/OUTPUT	
EXIT	

Items within the **SETUP** screen are described below:

Label	Settings/Range	Description
CO <sub>2</sub> ZERO NOW	Start or Cancel (default: Start)	Displays the <b>CO<sub>2</sub> ZERO NOW</b> screen. Place the CAPNOSTAT® CO <sub>2</sub> Sensor onto a clean and dry adapter. Place the adapter in room air and away from all sources of CO <sub>2</sub> . Select <b>START</b> to begin a CO <sub>2</sub> Zero or <b>CANCEL</b> to exit the selection and return to the <b>SETUP</b> menu.
PURGE NOW	n/a	The system immediately purges the CO <sub>2</sub> /Flow Sensor tubing. No messages are displayed. The Purge takes approximately 8 seconds. The flow and pressure waveform traces will return to zero during this period.
IABP Intra-Aorta Balloon Pump	ON or OFF	Displays the <b>SET SpO<sub>2</sub> IABP MODE</b> screen. Turn the <b>KNOB</b> to select <b>OFF</b> (default setting) or <b>ON</b> to turn off the validator algorithm so that all pulsatile data, including the normally rejected artifact generated by the IABP, are allowed to influence the SpO <sub>2</sub> and Pulse Rate calculations. Push the <b>KNOB</b> to accept your selection and return to the <b>SETUP</b> menu.
ERASE TRENDS	Yes or No (default: No)	Displays the <b>ERASE STORED TRENDS?</b> screen. Turn the <b>KNOB</b> to select <b>NO</b> (the default setting) or <b>YES</b> . Push the <b>KNOB</b> to accept your selection and return to the <b>SETUP</b> menu.
INPUT/OUTPUT	ANALOG OUT 1-4 ANALOG CAL. RS232-2/RS232-3	Turn the <b>KNOB</b> to select <b>ANALOG OUT 1</b> through <b>ANALOG OUT 4</b> , <b>ANALOG CAL.</b> , <b>RS232-2</b> or <b>R232-3</b> . Push the <b>KNOB</b> to accept your selection and assign it the desired output parameter.

Label	Settings/Range	Description
PULSE BEEP	OFF and 1-10 (default: OFF)	Displays the <b>SET PULSE BEEP</b> screen. Turn the <b>KNOB</b> to select a volume (1-10 and OFF) for the audible tone to accompany each detected pulse beat. Push the <b>KNOB</b> to accept your selection and return to the <b>SETUP</b> menu.
SWEEP	Slow, Medium, Fast (default: Medium)	Displays the <b>SET SWEEP SPEED</b> screen. Turn the <b>KNOB</b> to select how quickly the CO <sub>2</sub> , Flow and Pressure waveforms sweep across the display (Plethysmogram is unaffected). Push the <b>KNOB</b> to accept your selection and return to the <b>SETUP</b> menu.
SET SPON THRESHOLD	0-50 cmH <sub>2</sub> O	Displays the <b>SET SPONTANEOUS THRESHOLD</b> screen. The spontaneous threshold is the airway pressure chosen to help NICO® differentiate between a spontaneous breath and a mechanical breath. Turn the <b>KNOB</b> to adjust the setting indicated by a dashed line. For optimal setting of the spontaneous threshold, the dashed line should be above any spontaneous breaths and below the mechanical breaths. Push the <b>KNOB</b> to accept your selection and return to the <b>SETUP</b> menu.
SET TIME & DATE	hh:mm dd mmm yyyy	Displays the <b>SET TIME / DATE</b> screen. Turn the <b>KNOB</b> to highlight the portion of the time/date to change. Push the <b>KNOB</b> to select that item—it begins to flash. Turn the <b>KNOB</b> to adjust the flashing item, and when correctly set, push the <b>KNOB</b> again to accept the value. Repeat for the other time/date entries. Finally, turn the <b>KNOB</b> to highlight <b>EXIT</b> and push the <b>KNOB</b> to return to the <b>SETUP</b> menu.



## Notes on Patient Monitoring

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### Automatic Purging

A double lumen connecting line (tubing) connects the NICO® Flow and CO<sub>2</sub>/Flow sensors to the NICO® monitor. The NICO® monitor includes an automatic and manual purge feature which provides a flow rate of room air to keep the sensor tubing free from water condensation and patient secretions. This feature is available for the adult, pediatric, and neonatal modes.

#### Adult mode

The system automatically purges the sensor tubing every 10 minutes or less, depending on system conditions. In adult mode, the system will purge both sides of the line, one at a time, during each purge cycle. The higher the pressure, the more frequent the purging. This action anticipates increased moisture migration into the sensor tubing due to the increase in circuit pressure.

#### Neonatal and Pediatric modes

The automatic purge cycle used in the neonatal or pediatric mode is fixed at every 3 minutes regardless of circuit pressure. Only one side of the sensor tubing will be purged during each purge cycle. The purge will only occur during the exhalation portion of the ventilator cycle, regardless of exhalation time.

Unlike the adult purge mode, the neonatal or pediatric purge mode does not use the full force of the internal pump, but rather pressurizes an internal reservoir which is used for the purge. This minimizes the pressure delivered to the ventilator circuit, but does deliver a sufficient pressure to purge the sensor tubing.

### Manual Purging

Occasionally, purging may be required in between the automatic purge cycle. The manual purge may be used as often as needed, and may be used at all times **except** when a very low battery condition exists. During very low battery conditions, automatic and manual purging is not allowed.

To manually purge:

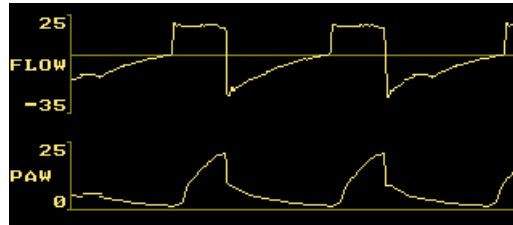
- 1 Press the **MENU** key.
- 1 Turn and press the **KNOB** to select **SETUP**.
- 1 Turn and press the **KNOB** to select **PURGE NOW**.
- 2 The purge cycle will begin:

In adult mode, the system will purge both sides of the line, one at a time, during each purge cycle.

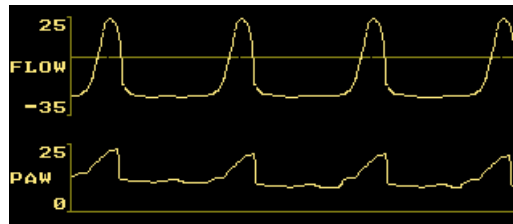
In pediatric and neonatal modes, only one side of the sensor tubing will be purged during each purge cycle. The purge is synchronized to the exhalation phase of the ventilator cycle and will not exceed exhalation time.

A purge can also be initiated upon request if the flow waveform appears as though the lines are partially occluded (see example below) and the purge did not initiate automatically. To initiate a purge, see Manual Purging, above.

Normal



Occluded

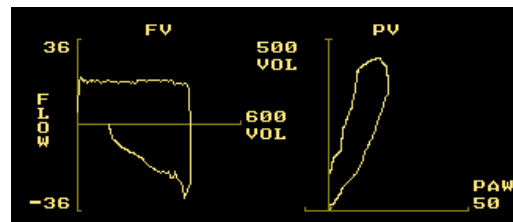


**NOTE:**

If the purge does not sufficiently clear the flow tubing lines, the flow sensor should be changed.

Below is an example of a waveform that exhibits a small leak in the breathing circuit. Replace the sensor; if problem persists, refer monitor to qualified service personnel.

Small leak  
in flow tubing



## Intra-Aortic Balloon Pump

NICO® uses advanced signal processing algorithms to distinguish valid pulsatile signals from signals generated by motion or other artifact. Motion artifact, very common in all but heavily sedated patients, can swamp the true pulsatile signal or distort it enough to produce significant errors in the SpO<sub>2</sub> and Pulse Rate calculations. The validator algorithms reject distorted plethysmographic signals or those that lack a regular rhythmic pattern; therefore, only valid (pulsatile) signals are allowed to affect the monitor's SpO<sub>2</sub> and Pulse Rate calculations. Rare conditions exist where the pulsatile waveform truly is distorted and lacks a fixed rhythm, specifically during use of an Intra-Aortic Pump (IABP).

During IABP procedures the pulsatile signal can be massively distorted without affecting the patient's SpO<sub>2</sub>. In order to accommodate these IABP procedures without compromising the monitor's superior artifact rejection algorithm, IABP MODE is available. IABP MODE allows the

user to turn off the validator algorithm so that all pulsatile data are allowed to influence the SpO<sub>2</sub> and Pulse Rate calculations.

**NOTE**

With IABP MODE turned ON, the clinician must exercise prudence in assessing the validity of the SpO<sub>2</sub> and Pulse Rate displays because any motion or other artifact—not just that associated with the IABP—can have a significant affect on the SpO<sub>2</sub> and Pulse Rate calculations.

While in IABP MODE, the displayed Pulse Rate reflects true pulsatile signal-heart rate plus the IABP ratio (e.g. #1: heart rate = 120 bpm, IABP ratio = 1:1, then displayed Pulse Rate should be  $120 + (120/1) = 240$  beats/min. e.g. #2: heart rate = 120 bpm, IABP = 1:3, then displayed Pulse Rate should be  $120 + (120/3) = 180$  beats/min). When in IABP MODE the Pulse Rate can be affected by motion or other artifact; the accuracy of the Pulse Rate can usually be used as an indicator of the quality of the SpO<sub>2</sub> display.

## Configuration Menu

Simultaneously press and hold the **MENU** and **DATA ENTRY** keys for 3 seconds to access the Configuration Menu. Turn and press the **KNOB** to adjust and accept settings.

Parameter	Range/Units	Description	Factory Default
CO <sub>2</sub> UNITS	mmHg, %, kPa	Select the desired units for the capnogram, PeCO <sub>2</sub> , ETCO <sub>2</sub> and PaCO <sub>2</sub> values.	mmHg
ETCO <sub>2</sub> AVG	10 sec, 20 sec, 1 Breath	Select the interval from which the displayed value of end tidal CO <sub>2</sub> (ETCO <sub>2</sub> ) is calculated.	10 sec
VCO <sub>2</sub> AVG	10 min, 7 min, 5 min, 3 min, 1 min, 8 Breath	Select the averaging time for the displayed value of CO <sub>2</sub> elimination (VCO <sub>2</sub> ).	1 min
ALLOW AUDIO OFF	N/A	When the ALLOW AUDIO OFF setting is set to YES, the audible alert tone may be silenced permanently by pressing and holding the SILENCE key.  If the ALLOW AUDIO OFF is set to NO, the audible alert tone may not be silenced for more than 2 minutes.	Yes
LANGUAGE	N/A	Select the desired language	English

## Reference Handbooks

For a discussion on waveform interpretations, refer to the Novamatrix Reference Handbooks on capnography, respiratory mechanics, and pulse oximetry. Contact Novamatrix Customer Service or your local sales representative for more information.



## Alerts

This section describes NICO® monitor alerts.

### NICO® Alert Priorities

The NICO® monitor prioritizes alert notifications. This prioritization allows an alert condition for which an immediate user response is required to take precedence over a lesser alert for which a less urgent response is acceptable. Alert notifications may include on-screen display messages and audible tones, and may result from violations of parameter limit settings, or from monitor or sensor related error conditions.

#### High Priority Alert

- Action: Immediate user response
- Audible: 3 consecutive tones, repeated every 5 seconds (if enabled)
- Visual: the **SILENCE** key indicator flashes red, and a screen message is displayed
- Example: **LOW C.O.**



#### Medium Priority Alert

- Action: Prompt user response
- Audible: 2 consecutive tones, repeated every 10 seconds (if enabled)
- Visual: Screen message
- Example: **HIGH RESP**

#### Low priority Alert

- Action: User awareness
- Audible: a single tone, repeated every 15 seconds (if enabled)
- Visual: Screen message
- Example: **EXPAND LOOP**

#### Status Messages

- Action: Informational, no urgency
- Audible: none
- Visual: Screen message
- Example: **ALERTS OFF**

## Responding to Alert Audio

The **SILENCE** key is used to mute/prevent audible alerts. It also visually indicates the presence of a "High Priority Alert". The Silence feature operates in two modes; a temporary "2 Minute Silence" mode and an "Audio Disabled" mode.



- 2 Minute Silence — Press and release to activate or deactivate the two minute silence. The key's icon illuminates amber when active and audible alerts will be muted for two minutes, after which the icon turns off and any active audible alert will sound.
- Audio Disabled — Press and hold for two seconds to prevent or allow any audible alerts. The key's icon illuminates and flashes amber to indicate that all audible alerts are being suppressed.
- High Priority Alerts — The **SILENCE** key's icon illuminates and flashes red to indicate High Priority Alert is active. The icon alternately flashes red and amber if the audio is disabled and a High Priority Alert is active.



## Parameter Limit Alerts

The NICO® monitor allows for the establishment of high and low limit alerts for Cardiac Output (C.O., Cardiac Output mode only), Positive Inspiratory Pressure (PIP, Respiratory Mechanics mode only), End-Tidal Carbon Dioxide (ETCO<sub>2</sub>), Oxygen Saturation (SpO<sub>2</sub>), Respiratory Rate (RR), and Pulse Rate (♥). These alerts provide a visual (and audible, if desired) indication to the user that a parameter has violated the limit settings

Cardiac Output mode			Respiratory Mechanics mode		
Parameter	Range	Units	Parameter	Range	Units
C.O.	OFF, 0.1 - 19.9	L/m	PIP	OFF, 5 - 120	cmH <sub>2</sub> O
ETCO <sub>2</sub>	OFF, 1 - 150 OFF, 0.1 - 19.9 OFF, 0.1 - 19.9	mmHg kPa %	ETCO <sub>2</sub>	OFF, 1 - 150 OFF, 0.1 - 19.9 OFF, 0.1 - 19.9	mmHg kPa %
SpO <sub>2</sub>	OFF, 50 - 100	%	SpO <sub>2</sub>	OFF, 50 - 100	%
RR	OFF, 3 - 150	br/min	RR	OFF, 3 - 150	br/min
♥ (Pulse Rate)	OFF, 31 - 249	bpm	♥ (Pulse Rate)	OFF, 31 - 249	bpm

- All alert limit values are retained each time the monitor is turned off.
- The user can select individual limit values or have the monitor automatically assign limit values based on current patient values with the **AUTO LIMITS** feature.
- Audible alarms can be enabled or disabled for each individual high and low limit setting.
- Limits cannot be adjusted to provide less than a 5 digit separation between the high and low limit values.
- Violating the 5-digit minimum separation constraint may cause previously set alerts to reset or turn off.

### NOTE

The message **ALERTS OFF** will appear if the monitor is powered up with all alert limits and audible alerts set to **OFF**.

To cancel the **ALERTS OFF** message, adjust any individual limit value and activate the audible alert (🔔). Both the alert limit and audible alert must be activated.

### View Alert Settings

To view the existing alert settings:

- 1 Press the **MENU** key. The **SELECT A SCREEN** menu appears.
- 2 Highlight and then select **SET ALERTS** by turning and then pressing the knob.
- 3 The **SET ALERTS** screen is displayed.

### Adjust Alert Limits

To adjust **LOW** or **HIGH** alert limit values:

- 1 Display the **SET ALERTS** screen. (Press **MENU**, then select **SET ALERTS**.)
- 2 Highlight and then select the **LOW** or **HIGH** limit you wish to adjust (PIP is **HIGH** only).
- 3 Turn the knob to adjust the limit, then press the knob to accept the displayed value.
- 4 If desired, enable the audio for the alerts which have been enabled. (See below.)

### Enable/Disable Audible Alerts

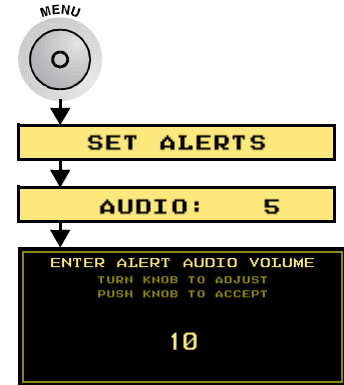
To enable or disable the audible alert tone(s) for a particular alert:

- 1 Display the **SET ALERTS** screen. (Press **MENU**, then select **SET ALERTS**.)
- 2 Highlight the bell icon for the alert you wish to adjust.
- 3 Press the knob to switch between audio enabled (🔔) and disabled (🔕) settings.

### Adjust Alert Audio Volume

To adjust the Alert Audio Volume:

- 1 Display the **SET ALERTS** screen. (Press **MENU**, then select **SET ALERTS**.)
- 2 Highlight and then select **AUDIO** by turning and then pressing the knob.
- 3 Turn the knob to adjust the volume setting.
  - Volume ranges from 1 to 10 (loudest).
  - A representative tone sounds at each setting.
- 4 Press the knob to accept the displayed value.



#### NOTE

Make sure that the audible alert volume is not set too low to be heard over ambient noise levels.

### Auto Alerts

Alert limits for **LOW** and **HIGH** C.O., PIP (**HIGH** only), ETCO<sub>2</sub>, SpO<sub>2</sub>, RR and Pulse rate can be set automatically for alerts which have been enabled. Alert limits are bracketed about the current patient values. Auto Alerts do not affect the status of the audible alert bell icon.

## No Respiration Alert

The NICO® monitor incorporates a No Respiration Alert (**NO RESP**). Once the monitor detects respiration, any loss of that signal starts the "No Resp" timer. A visual (and audible, if desired) alert occurs if the monitor does not detect a respiratory rate signal before the timer reaches its user set limit (20 seconds by default).



If a No Respiration alert occurs:

- The message **NO RESP: x:xx** is displayed (unless a higher priority alert is in progress).
- The counter shows the elapsed time (minutes:seconds) since the alert occurred.
- Press the **SILENCE** key to cancel the alert.
- The alert (message, audio and flashing **SILENCE** key) is automatically cancelled after ten minutes.



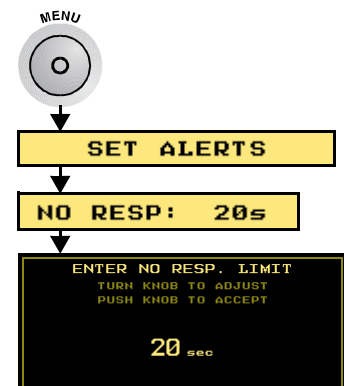
#### WARNING

The NICO® monitor is not intended to be used as an apnea monitor.

### Adjust the No Resp. Alert Limit

To adjust the No Respiration Alert Limit:

- 1 Display the **SET ALERTS** screen. (Press **MENU**, then select **SET ALERTS**.)
- 2 Highlight and then select **NO RESP** by turning and then pressing the knob.
- 3 Turn the knob to adjust the limit setting.
  - The limit timer is selectable from 10-60 seconds.
- 4 Press the knob to accept the displayed value.





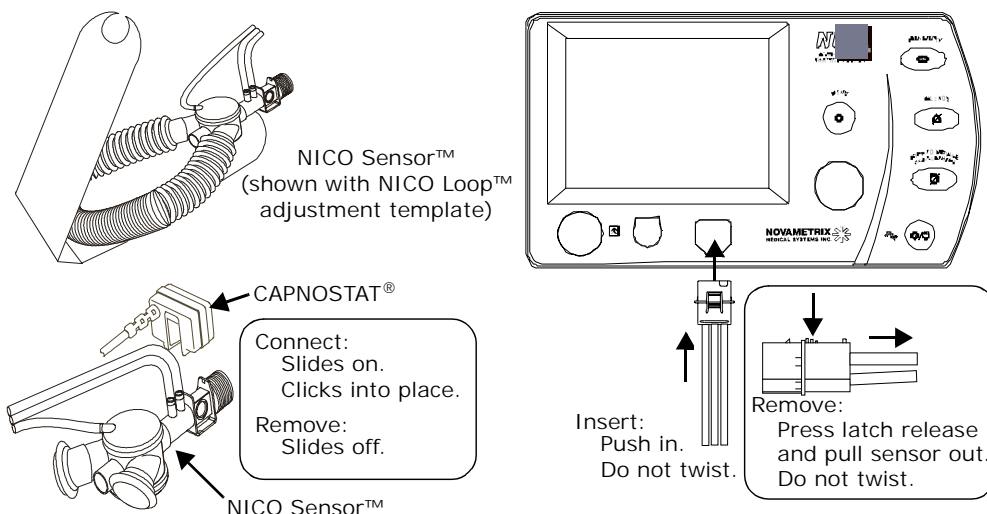
## NICO Sensor™

This section provides information regarding Disposable NICO Sensors™ and their use with the CAPNOSTAT® CO<sub>2</sub> Sensor and the NICO® monitor.

### Disposable NICO Sensors™

A NICO Sensor™ incorporates a rebreathing valve, NICO Loop™ (an adjustable rebreathing volume) and an adult CO<sub>2</sub>/Flow Sensor. It is disposable and intended for Single Patient Use only. The NICO Sensor™ is not for pediatric use.

A NICO Sensor™ may be connected to and removed from the NICO® monitor while the monitor is turned off or on.



#### WARNING

The Disposable NICO Sensor™ is intended for SINGLE PATIENT USE ONLY (X).

Re-use, including disassembly, cleaning, disinfecting, sterilizing, and other efforts made in an attempt to re-use a NICO Sensor™, may compromise system performance and may cause a potential patient hazard. Performance is not guaranteed if reused.

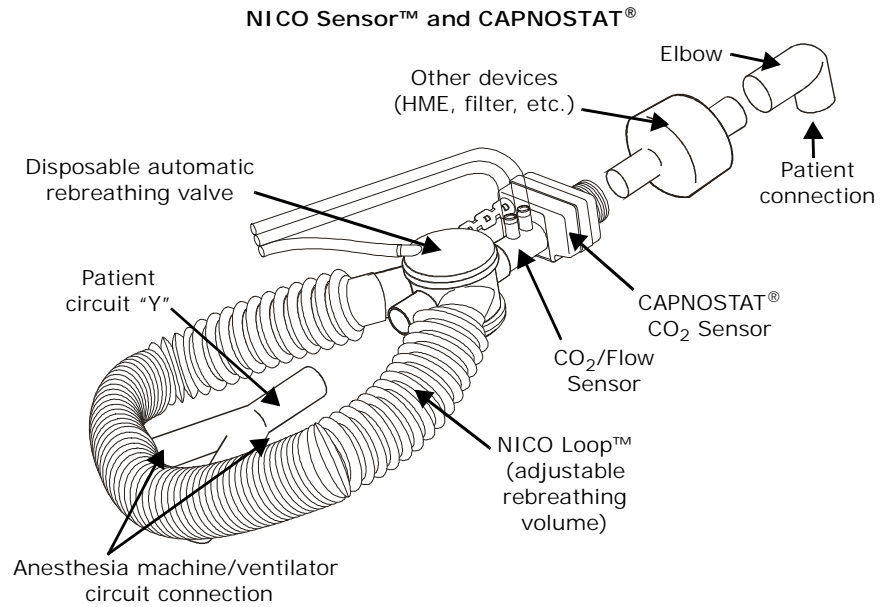
Before use, verify the sensor is physically intact, with no broken or damaged parts. Do not use a broken or damaged sensor or one with wet, contaminated, or corroded connectors.

Do not allow the NICO Sensor™ to remain in the ventilator circuit when not connected to the NICO® monitor. A ventilator circuit leak will occur.



#### CAUTION

Connect only a Novamatrix NICO Sensor™, Catalog Number 8950-00, 8951-00 or 8952-00 to the NICO® monitor. Do not connect any other sensor in place of a NICO Sensor™.



### Choosing a NICO Sensor™ size

Choose a NICO Sensor™ size based on the tidal volume ranges listed below.

Sensor Size	Tidal Volume Range	Part Number
Small	For use with ventilator set tidal volumes of 200-500 ml	8950-00
Standard	For use with ventilator set tidal volumes of 400-1000 ml	8951-00
Large	For use with ventilator set tidal volumes of 750-1500 ml	8952-00



#### WARNING

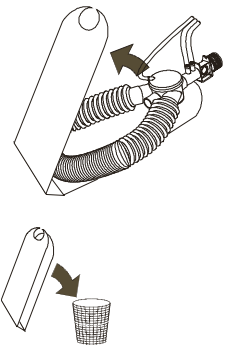
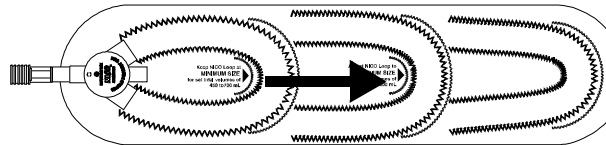
The NICO Sensor™ is not for pediatric use.

The NICO Sensor™ increases airway deadspace by 35 cc (minimum). At low tidal volumes, compensatory changes to ventilation protocol should be considered.

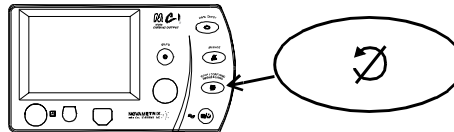
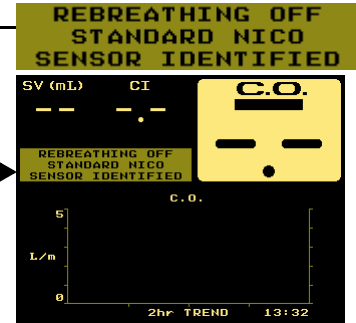
### Connecting a NICO Sensor™

To connect a NICO Sensor™ into the ventilator circuit:

- 1 Remove a new NICO Sensor™ and loop adjustment template from its package. Open and inspect the sensor. Do not use if damaged.
- 2 Using the Initial Adjustment Template as a guide, adjust the NICO Loop™ to match the ventilator's tidal volume setting. Discard the template.



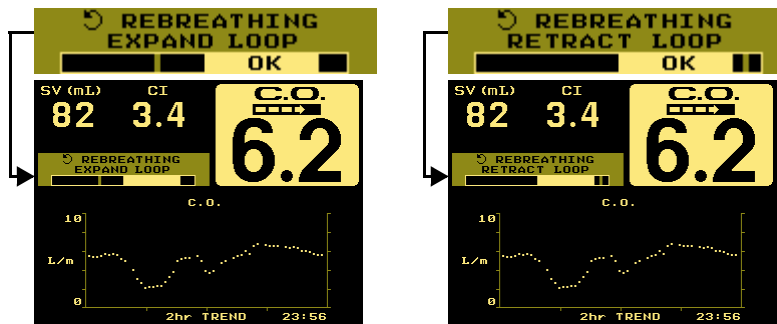
- 3 Insert the connector on the NICO Sensor™ into NICO® monitor's front panel. Verify a **NICO SENSOR IDENTIFIED** message is briefly displayed.
- 4 Attach the CAPNOSTAT® to the NICO Sensor™ and connect the NICO Sensor™ to ventilator circuit. For optimal results, place the NICO Sensor™ into the ventilator circuit between the endotracheal tube and the ventilator circuit wye.
  - Place other devices (HME, filters, etc.) between NICO Sensor™ and the patient connection.
  - Placement of a sidestream gas analyzer sampling port between the NICO Sensor™ and the patient connection may reduce NICO® accuracy at low tidal volumes.
  - Sidestream or mainstream gas analyzers placed between the NICO Sensor™ and the patient circuit "Y" may report diluted readings during the rebreathing phase of the NICO® cycle.
  - Place the sensor so that the triple lumen tubing lines exit from the top of the sensor (to help keep them clear and dry).
  - Keep the sensor clear of accumulations by proper circuit maintenance.
- 5 To begin monitoring, press the **STOP / CONTINUE REBREATHING** key.



- To enhance accuracy, enter the respiratory gas composition and the arterial blood gas values whenever possible (by pressing the **DATA ENTRY** key).

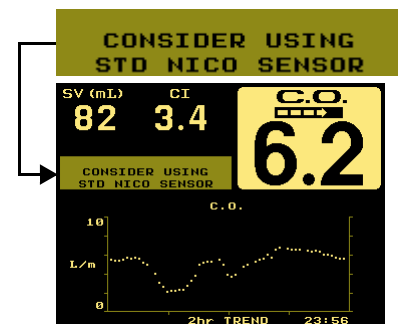
## Status Messages

While monitoring, if the **EXPAND** or **RETRACT LOOP** message appears, adjust the loop 3-6 inches (8-15 cm) or until the message is removed.



If the **EXPAND** or **RETRACT LOOP** message appears for more than three consecutive rebreathing cycles, and resizing the NICO Loop™ was not effective, the NICO® monitor will suggest a different sized sensor, with a larger or smaller loop, to correct the condition.

- Small NICO Sensor™: the monitor displays **CONSIDER USING A STANDARD NICO SENSOR** when ventilator set tidal volume is greater than 500 ml.
- Standard NICO Sensor™: the monitor displays **CONSIDER USING A SMALL NICO SENSOR** when ventilator set tidal volume is less than 300 ml.
- Standard NICO Sensor™: the monitor displays **CONSIDER USING A LARGE NICO SENSOR** when ventilator set tidal volume is greater than 1000 ml.
- Large NICO Sensor™: the monitor displays **CONSIDER USING A STANDARD NICO SENSOR** when ventilator set tidal volume is less than 1000 ml.

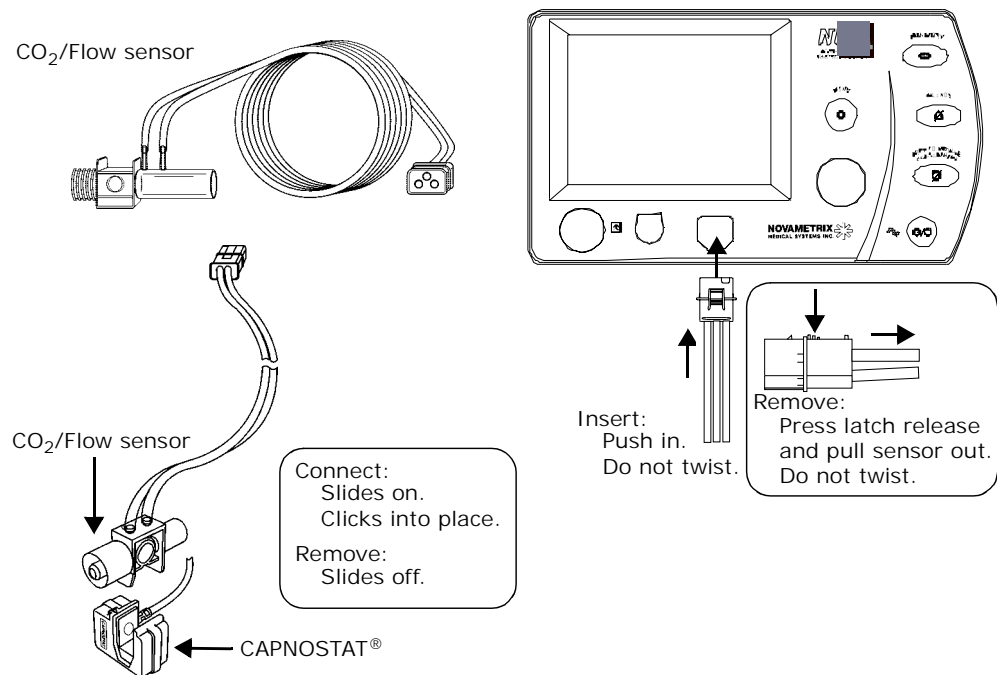




## CO<sub>2</sub>/Flow Sensors

This section details the use of combined CO<sub>2</sub>/Flow sensors with the NICO® monitor. This section also explains how to connect a sensor to the monitor, and how to apply the sensor to the patient. NICO® automatically operates in Respiratory Mechanics mode whenever a CO<sub>2</sub>/Flow sensor is connected to the monitor. Cardiac output and associated parameters are no longer available.

Only NICO® CO<sub>2</sub>/Flow sensors are compatible with the NICO® monitor. Sensors may be connected and removed with the monitor off or on.



### WARNING

The Disposable CO<sub>2</sub>/Flow sensor is intended for SINGLE PATIENT USE ONLY ②.

Re-use, including disassembly, cleaning, disinfecting, sterilizing, and other efforts made in an attempt to re-use a CO<sub>2</sub>/Flow sensor, may compromise system performance and may cause a potential patient hazard. Performance is not guaranteed if reused.

Before use, verify the sensor is physically intact, with no broken or damaged parts. Do not use a broken or damaged sensor or one with wet, contaminated, or corroded connectors.

Do not allow the CO<sub>2</sub>/Flow sensor to remain in the ventilator circuit when not connected to the NICO® monitor. A ventilator circuit leak will occur.

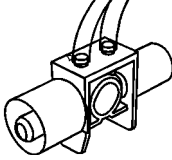
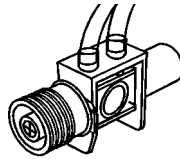
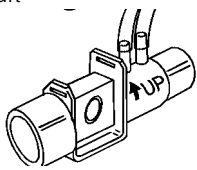


#### CAUTION

Connect only Novamatrix NICO® CO<sub>2</sub>/Flow sensors, Catalog Number 9765-00, 9766-00, or 9767-00, to the NICO® monitor. Do not connect any other sensor in place of a NICO CO<sub>2</sub>/Flow sensor.

## Choosing a CO<sub>2</sub>/Flow Sensor

Select the appropriate combined CO<sub>2</sub>/Flow sensor based on endotracheal tube size (ETT), volume and flow rate. Ranges for each sensor are listed in the chart below:

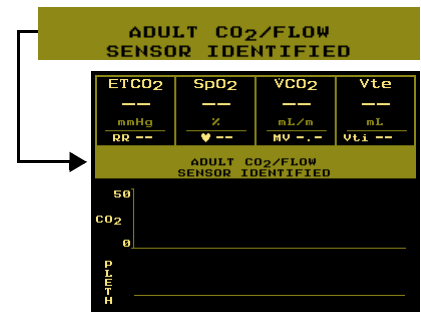
Sensor	Range			
	ETT (mm)	Volume (ml)	Flow	Deadspace
Neonatal 	2.5-4.0	1-100	0.25-25 LPM 4-417 ml/sec	Less than 1 ml
Catalog No. 9765-00				
Pediatric 	3.5-6.0	30-400	0.5-100 LPM 8-1600 ml/sec	Less than 4 ml
Catalog No. 9766-00				
Adult 	>5.5	200-3000	2.0-180 LPM 33-3000 ml/sec	Less than 8.5 ml
Catalog No. 9767-00				

## Connecting a CO<sub>2</sub>/Flow Sensor

To connect a combined CO<sub>2</sub>/Flow sensor:

- 1 Remove a new CO<sub>2</sub>/Flow sensor from its package. Open and inspect the sensor. Do not use if damaged.
- 2 Insert the connector on the CO<sub>2</sub>/Flow sensor into NICO® monitor's front panel. Verify a **CO<sub>2</sub>/FLOW SENSOR IDENTIFIED** message is briefly displayed.
- 3 Attach the CAPNOSTAT® to the CO<sub>2</sub>/Flow sensor. The sensor will "click" when properly seated.

When a CO<sub>2</sub>/Flow sensor is replaced, the message **CHECK/CHANGE AIRWAY ADAPTER** may appear, this means a CO<sub>2</sub> zero is required to help the NICO® monitor "learn" the specific optical characteristics of the CO<sub>2</sub>/Flow sensor in use.



To perform an Adapter Zero:

- 1 Press the **MENU** key.
- 2 Highlight and then select **SETUP** by rotating and then pressing the knob.
- 3 Highlight and then select **CO<sub>2</sub> ZERO NOW**.
- 4 Place the CAPNOSTAT® onto a clean and dry CO<sub>2</sub>/Flow sensor (adapter) that is exposed to room air and away from all sources of CO<sub>2</sub>. Alternatively, the CO<sub>2</sub> adapter provided with the CAPNOSTAT® can be used for the zero procedure.
- 5 Highlight and then select **START**.
  - **ADAPTER ZERO IN PROGRESS PLEASE WAIT** is displayed during the 10 seconds needed to complete the process. Upon completion, **ADAPTER ZERO SUCCESSFUL** is briefly displayed before the monitor automatically returns to the **SETUP** screen.
- 6 Highlight and then select **EXIT** to return to the previous monitoring screen.



**CAUTION**

Position the airway adapter with its windows in a vertical and NOT a horizontal position: this helps keep patient secretions from “pooling” on the windows.

To prevent “rain-out” and moisture from draining into the airway adapter, do NOT place the airway adapter in a gravity dependent position.

Periodically check the CO<sub>2</sub>/Flow sensor and tubing for excessive moisture or secretion build up.



The CAPNOSTAT®



## CAPNOSTAT® CO<sub>2</sub> Sensor

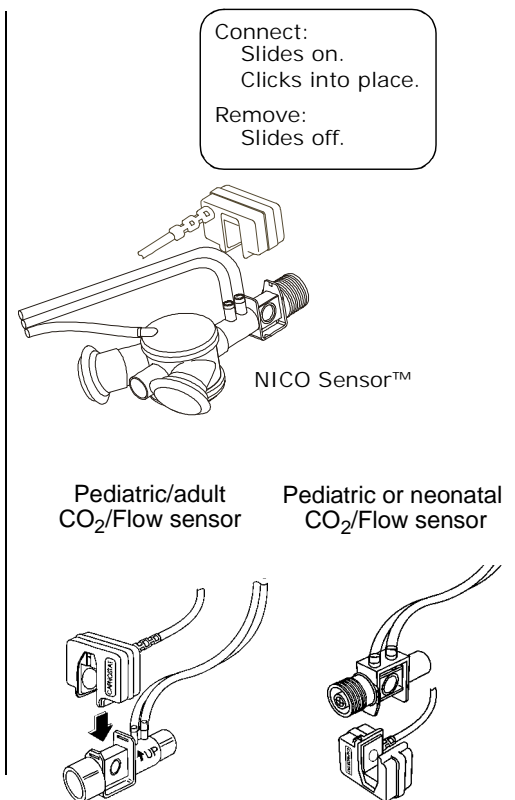
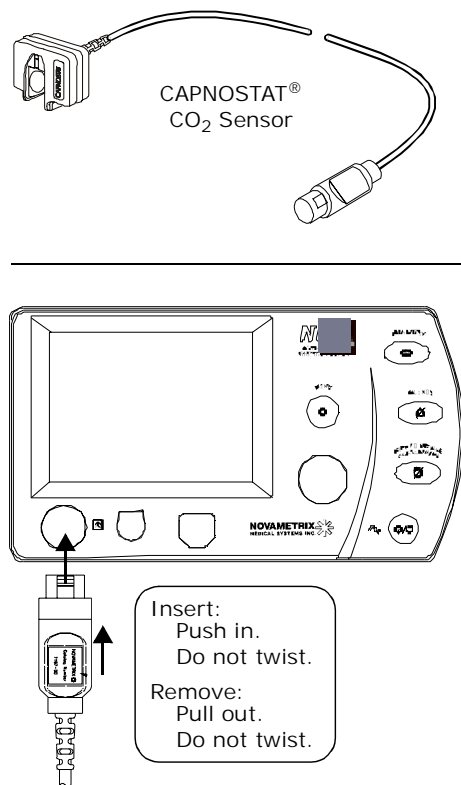
This section provides information regarding the CAPNOSTAT® CO<sub>2</sub> Sensor and its use with NICO Sensors™ and the NICO® monitor.

### The CAPNOSTAT®

The CAPNOSTAT® CO<sub>2</sub> Sensor is a rugged, solid-state, mainstream sensor. It is factory calibrated and does *not* require further calibration during use.

#### Connecting the CAPNOSTAT®

The CAPNOSTAT® may be connected to and removed from the NICO® monitor while the monitor is turned off or on.



#### CAUTION

Connect only a Novametrix CAPNOSTAT® CO<sub>2</sub> Sensor, Catalog Number 9567-00, to the NICO® monitor. Do not use other CAPNOSTAT® types or other CO<sub>2</sub> sensors.



#### WARNING

Before use, verify the sensor is physically intact, with no broken/frayed wires or damaged parts. Do not use a broken or damaged sensor or one with wet, contaminated, or corroded connectors.

## CAPNOSTAT® Adapter Zero

An “Adapter Zero”, a quick 15 second process that lets the NICO® monitor “learn” the special characteristics of a particular CAPNOSTAT®, is necessary only when the NICO® monitor requests an Adapter Zero.

Such a request may occur the first time a particular CAPNOSTAT® is connected to a particular NICO® monitor—as is the case the first time you power up your NICO® monitor and CAPNOSTAT®—or if the monitor detects some change in the CAPNOSTAT®.

Once an Adapter Zero is performed, NICO® can be turned on and off and the CAPNOSTAT® can be unplugged and reconnected without having to calibrate or Adapter Zero sensor. However, if a second CAPNOSTAT® is connected in place of the first, the Adapter Zero process must be performed on the new sensor—and if at a later time, the first CAPNOSTAT® is reconnected, it too will then have to be put through the Adapter Zero process.



### Adapter Zero

To perform an Adapter Zero:

- 1 Press the **MENU** key.
- 2 Highlight and then select **SETUP** by rotating and then pressing the knob.
- 3 Highlight and then select **CO2 ZERO NOW**.
- 4 Place the CAPNOSTAT® onto a clean and dry NICO Sensor™ or CO<sub>2</sub>/Flow sensor (adapter) that is exposed to room air and away from all sources of CO<sub>2</sub>. Alternatively, a Single Patient Use Adult Airway Adapter (Cat. No. 6063-01) provided with the CAPNOSTAT® can be used for the zero procedure.
- 5 Highlight and then select **START**.
  - **ADAPTER ZERO IN PROGRESS PLEASE WAIT** is displayed during the 10 seconds needed to complete the process. Upon completion, **ADAPTER ZERO SUCCESSFUL** is briefly displayed before the monitor automatically returns to the **SETUP** screen.
- 6 Highlight and then select **EXIT** to return to the previous monitoring screen.

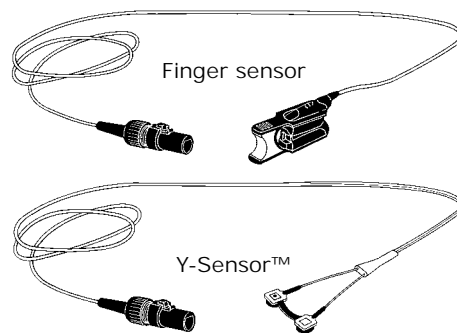


## Pulse Oximetry Sensors

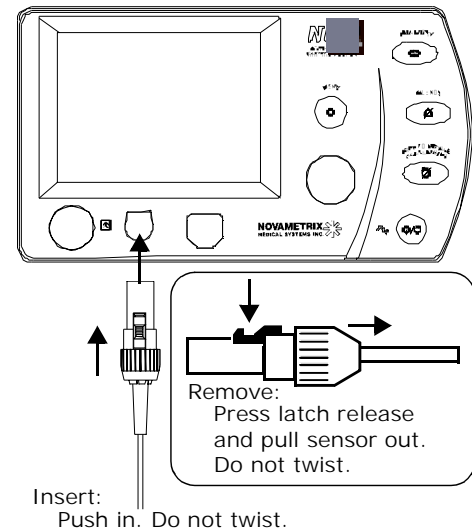
This section details the various pulse oximetry sensors and accessories that can be used with the NICO® monitor. This section also explains how to connect a sensor to the monitor, and how to apply the sensor to the patient. NICO® uses the pulse oximeter portion of the monitor to enhance shunt corrections as well as to monitor patient oxygenation levels.

### Oximetry Sensors

NICO is compatible with a variety of Novametrix pulse oximetry sensors including reusable Finger and Y-Sensors™ and Single Patient Use sensors.



Sensors may be connected and removed with the monitor off or on.



#### CAUTION

Connect only Novametrix SuperBright™ SpO<sub>2</sub> sensors, extension cables and accessories with the NICO® monitor. Do not use other SpO<sub>2</sub> sensors or accessories.

Overstretching the pulse oximeter finger sensor can damage the sensor and potentially affect pulse oximeter readings. Do not stretch the finger sensor open beyond the limit for which it was designed. Overstretching can be prevented: avoid opening the sensor by any means other than squeezing the grips; *DO NOT* force the sensor onto large objects such as a bedrail.



#### WARNING

Before applying to the patient, verify the sensor is physically intact, with no broken/frayed wires or damaged parts. Do not use a broken or damaged sensor or one with wet, contaminated, or corroded connectors.

After applying to the patient, inspect the site often for adequate circulation—at least once every four hours. Do not wrap so tightly that circulation is restricted. Note the patient's physiological condition. For example, burn patients may be more sensitive to heat and pressure and require more frequent site checks.

## Finger Sensor

### Sensor Quick Check

A quick functional check of basic sensor operation.

- 1 With the sensor connected to the monitor but not applied to the patient, position the sensor heads so they face each other (red light shines on the detector). Is **PULSE SEARCH** displayed?
- 2 Apply the sensor to your finger. Are reasonable SpO<sub>2</sub> and pulse rate values displayed?
- 3 A YES to BOTH #1 and #2 indicates the sensor is operational. Apply the sensor to the patient as instructed.
  - Note that the Quick Check tag on the sensor may refer to the message **Probe Off Patient**. This message does not apply to the NICO® monitor—**PULSE SEARCH** does.

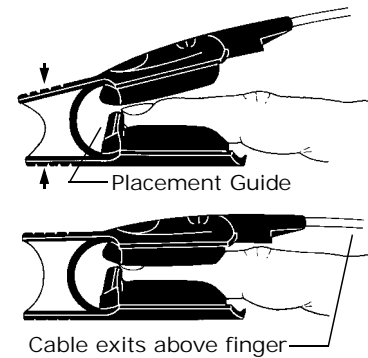
## Finger Sensor

The reusable Finger Sensor is intended for adult and appropriately sized pediatric fingers and is not intended for neonatal applications.

To apply: Squeeze the grips. Position the fingertip as shown and release the grips.

To remove: Squeeze the grips. Slide the sensor from the finger and release the grips.

Caution: Overstretching can damage the sensor and affect oximetry readings. Do not force the sensor onto large objects such as bedrails.

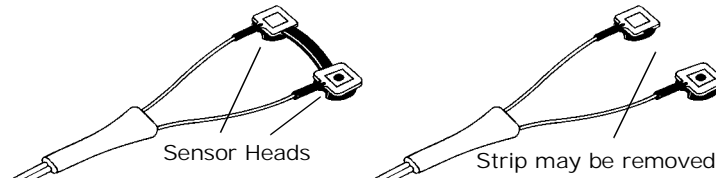


## Y-Sensor™

The reusable Y-Sensor™ is designed for use on all patients from adults to neonates.

### Y-Sensor™ configuration

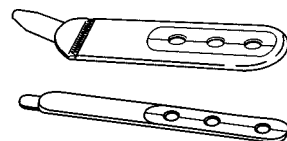
The Y-Sensor's™ center strip may be carefully cut away if the distance between the sensor heads needs to be reduced to less than 25mm.



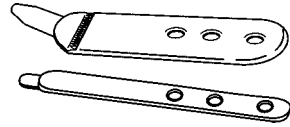
### Y-Sensor™ applicators

The flexible and versatile Y-Sensor™ is applied to the patient using a variety of adhesive and non-adhesive applicators.

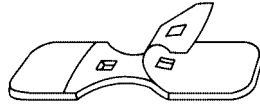
Treat applicators (except ear-clip) in accordance with hospital protocol for single-patient use. Refer to instructions packaged with the various applicators.



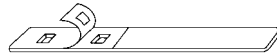
- 6929-00. Adhesive Foam Wraps, Large  
— Adult, pediatric or neonatal use.
- 6968-00. Adhesive Foam Wraps, Small  
— Neonatal or appropriately sized pediatric patient.



- 8836-00. Non-Adhesive Foam Wrap, Large  
— Adult, pediatric or neonatal use.
- 8943-00. Non-Adhesive Foam Wrap, Small  
— Neonatal or appropriately sized pediatric patient use.

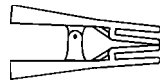


- 8831-00. 20mm Finger Style Y-Strip™ Tape (blue)  
— Appropriately sized pediatric or adult fingers.
- 8832-00. 25mm Finger Style Y-Strip™ Tape (green)  
— Adult fingers.



- 8828-00: Wrap Style Tapes 20mm (blue).  
— Neonatal foot, hand, pediatric toe, finger
- Catalog No. 8829: 25mm (green)  
— Neonatal foot, hand

Size refers to the distance between the holes in the tape.

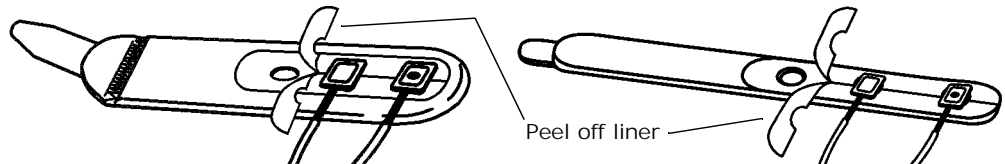
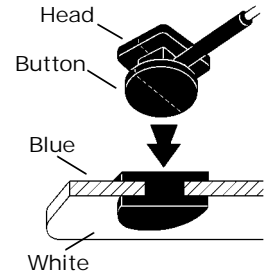


- 6131-00. Ear Clip  
— Adult or pediatric use.

## Using Foam Wraps

To use the foam wraps;

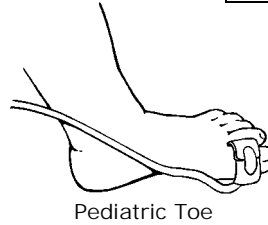
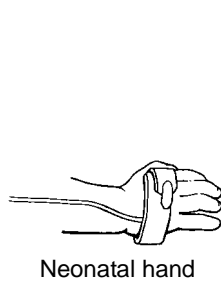
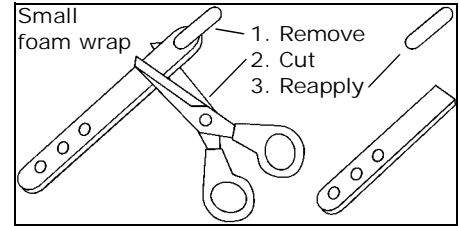
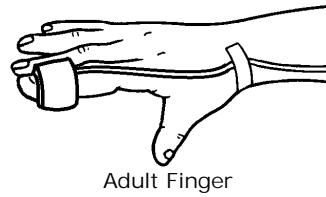
- 1 Press each sensor “button” through the blue side of the foam wrap.
  - Place the head with the red LED closest to the edge, and the other in either remaining hole (removing the Y-Sensor's™ center strip as required).
- 2 If using an adhesive foam tape, remove both sides of the paper liner.
  - You can also remove the liners prior to buttoning the sensor into the foam wrap if desired.



- 3 With the blue foam towards the patient, wrap around the site. Ensure the sensor heads are opposite each other through the tissue. Secure in place with the white plastic tab.

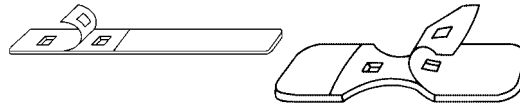
Y-Sensor™

- The tab on the Small foam wrap is removable, allowing shortening for a better fit. Reapply the tab to secure the wrap in place.



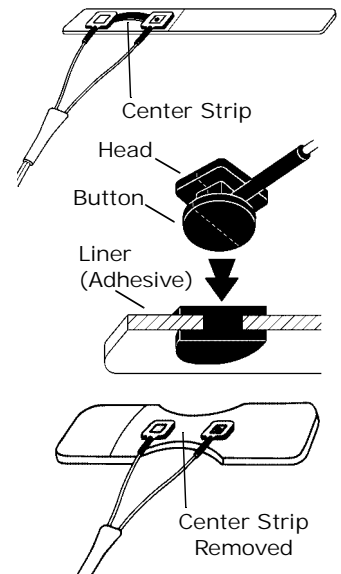
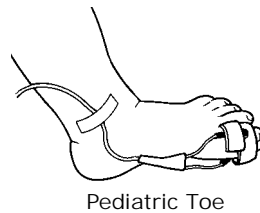
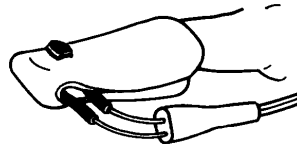
### Using Y-Strip™ Tapes To use the Y-Strip™ Tapes;

- 1 Remove the release liner with the holes.



- 2 Press each sensor "button" through the adhesive side of the tape. (Remove the Y-Sensor's™ center strip if required.)
- 3 Remove the remaining release liner. Apply the sensor/ tape to the patient. Ensure the sensor heads are opposite each other.

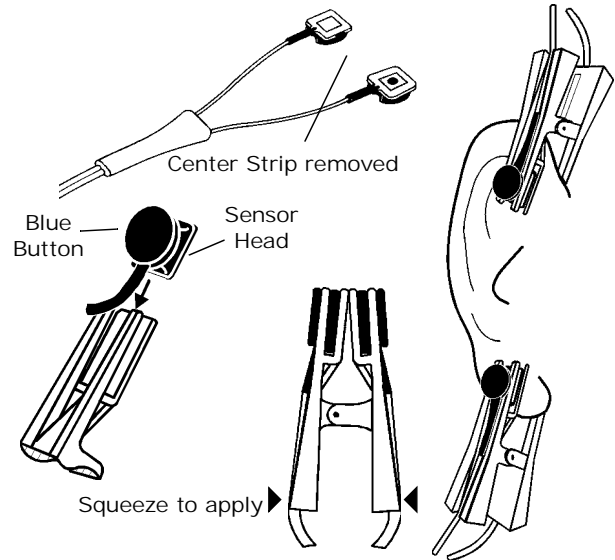
Adult/Pediatric Finger



## Using the Ear Clip

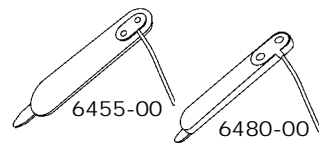
To use the ear clip;

- 1 Remove the center strip from the Y-Sensor™.
- 2 Slide each Y-Sensor™ head into an Ear Clip receptacle with the blue button facing outwards.
- 3 Open the clip by squeezing its ends and apply it to the ear.
  - It may be necessary to rub the ear with your fingers in order to increase circulation prior to applying the sensor.
  - Adhesive Dots (8700-00) are included with the ear clip to help hold the clip to the ear.



## Single Patient Use Sensors

These Single Patient Use Sensors are for use on appropriately sized patients.



- 6455-00. Pediatric/Adult, Foam Wrap Style  
— Adult or appropriately sized pediatric patients.
- 6480-00. Neonatal/Pediatric, Foam Wrap Style  
— Neonatal or appropriately sized pediatric patients.

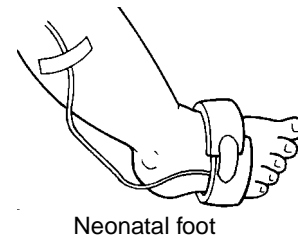
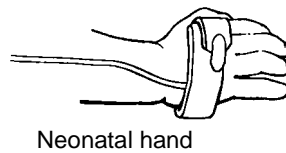
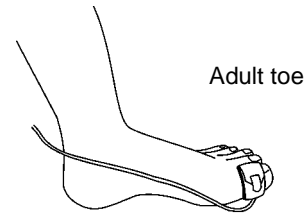
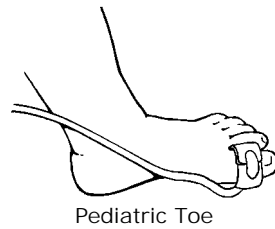
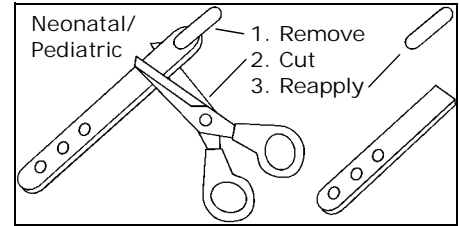
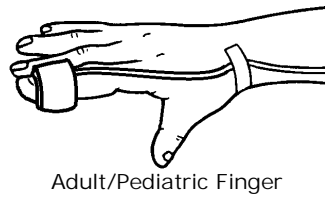
### CAUTION:



Single Patient Use SpO<sub>2</sub> sensors can be reapplied to a single patient as needed, but should not be used across multiple patients. Single Patient Use sensors should not be cleaned or disinfected. System performance may be compromised as a result. Replace sensor instead.

- 1 Select the appropriate size sensor based on the patient type.
- 2 With the blue foam towards the patient, wrap around the site. Ensure the sensor heads are opposite each other through the tissue. Secure in place with the white plastic tab.
  - Double-sided adhesive dots, included with the sensor, can be applied over the LED and detector components to help hold the sensor to the site.

- The tab on the Neonatal/Pediatric sensor is removable, allowing shortening for a better fit. Reapply the tab to secure the sensor in place.





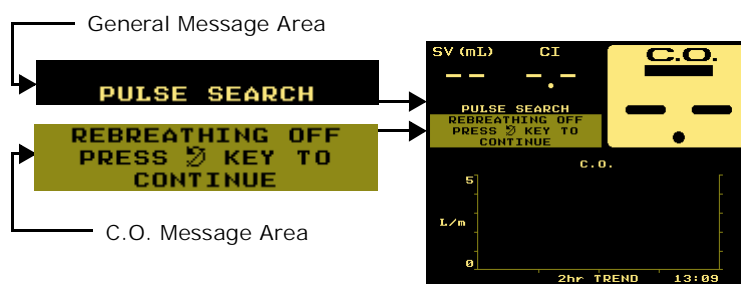


## Messages

### Message Areas - Cardiac Output mode

For Respiratory Mechanics messages, see page 78.

In Cardiac Output mode, the monitor uses two screen locations, the General Message Area and the C.O. Message Area, to convey information to the user.



#### General Message Area

The General Message Area in Cardiac Output mode displays system status, alert, and error conditions. It may be blank or:

- contain 1 single-line message
- contain 2 single-line messages
- contain 1 multi-line message



The General Message Area messages are listed below, in alphabetical order.

(Alert Class: H-High Priority, M-Medium Priority, L-Low Priority, S-Status Message. See "NICO® Alert Priorities" on page 56 for details.)

General Message Area	Message Description	Alert Class
ALERTS OFF	Displayed as a reminder that the default for all user selectable alerts is OFF. To cancel the message, adjust any individual limit value and activate the audible alert. Both the alert limit and audible alert must be activated.	S
AMBIENT LIGHT COVER SpO <sub>2</sub> PROBE	The monitor detects interference on the SpO <sub>2</sub> sensor from ambient light. This can be corrected by covering the SpO <sub>2</sub> sensor, or possibly by changing the sensor site.	S
CHECK / CHANGE AIRWAY ADAPTER	A change in the CO <sub>2</sub> adapter portion of the NICO Sensor™ is detected. Possible causes: <ul style="list-style-type: none"> <li>• CAPNOSTAT® CO<sub>2</sub> sensor off adapter</li> <li>• High level of moisture and/or secretions in the adapter. The moisture can be drained from the NICO Sensor™ and re-inserted in the circuit. Facing the pneumatic tubing upward as it exits the NICO Sensor™ can minimize this.</li> </ul>	S

General Message Area	Message Description	Alert Class
CO <sub>2</sub> SENSOR FAILURE REPLACE SENSOR	A problem with the CAPNOSTAT® CO <sub>2</sub> sensor has been identified. Replace the CAPNOSTAT® and return it to Novamatrix for exchange or repair.	M
CO <sub>2</sub> SENSOR?	The CAPNOSTAT® CO <sub>2</sub> sensor is not connected to the NICO® monitor.	S
CO <sub>2</sub> ZERO REQUIRED (MENU→SETUP)	The CAPNOSTAT® CO <sub>2</sub> sensor needs to be zeroed. Press the <b>MENU</b> key, then select <b>SETUP</b> , then <b>CO2 ZERO NOW</b> , and follow the instructions on the screen. NOTE: the CO <sub>2</sub> adapter provided with the CAPNOSTAT® can be used for the CO <sub>2</sub> zero procedure rather than a new NICO Sensor™.	S
DEMO MODE	The monitor is in demonstration mode and is not displaying patient data (all data is simulated). To exit demo mode, turn the monitor off, then back on.	S
ETCO <sub>2</sub> : XX mmHg	End tidal CO <sub>2</sub> is greater than 60 mmHg or exceeds the high alert limit. Appears in the general message area to supplement screens that do not display the ETCO <sub>2</sub> value.	L
HIGH C.O.	The displayed cardiac output value is above the set alert limit in the <b>SET ALERTS</b> screen (press <b>MENU</b> key, then select <b>SET ALERTS</b> to view the alert limit settings).	M
HIGH ETCO <sub>2</sub>	The displayed ETCO <sub>2</sub> value is above the set alert limit in the <b>SET ALERTS</b> screen (press <b>MENU</b> key, then select <b>SET ALERTS</b> to view the alert limit settings).	H
HIGH PULSE	The displayed pulse rate value is above the set alert limit in the <b>SET ALERTS</b> screen (press <b>MENU</b> key, then select <b>SET ALERTS</b> to view the alert limit settings).	M
HIGH RESP RATE	The displayed respiration rate value is above the set alert limit in the <b>SET ALERTS</b> screen (press <b>MENU</b> key, then select <b>SET ALERTS</b> to view the alert limit settings).	M
HIGH SpO <sub>2</sub>	The displayed SpO <sub>2</sub> value is above the set alert limit in the <b>SET ALERTS</b> screen (press <b>MENU</b> key, then select <b>SET ALERTS</b> to view the alert limit settings).	M
INCOMPATIBLE CO <sub>2</sub> SENSOR	The wrong part number CAPNOSTAT® is connected to the NICO® monitor. Use only a CAPNOSTAT® with part number 9567-00 (this can be distinguished from other CAPNOSTAT® part numbers by the yellow part number label on the CAPNOSTAT®'s electrical connector).	M
INCOMPATIBLE FLOW SENSOR	The wrong flow sensor is connected to the NICO® monitor. Use only a NICO Sensor™, part numbers 8950-00, 8951-00 or 8952-00 (the correct flow sensor is an integral part of the NICO Sensor™).	M
INSP CO <sub>2</sub> : xx	(where xx is a numeric value with units of mmHg, kPa, or %). At least 3 mmHg, 0.1% or 0.1 kPa of CO <sub>2</sub> has been detected during inspiration (other than during rebreathing) for at least ten continuous seconds.	S
LOW C.O.	The displayed cardiac output value is below the set alert limit in the <b>SET ALERTS</b> screen (press <b>MENU</b> key, then select <b>SET ALERTS</b> to view the alert limit settings).	H
LOW ETCO <sub>2</sub>	The displayed ETCO <sub>2</sub> value is below the set alert limit in the <b>SET ALERTS</b> screen (press <b>MENU</b> key, then select <b>SET ALERTS</b> to view the alert limit settings).	M
LOW PULSE	The displayed pulse rate value is below the set alert limit in the <b>SET ALERTS</b> screen (press <b>MENU</b> key, then select <b>SET ALERTS</b> to view the alert limit settings).	H


General Message Area	Message Description	Alert Class
LOW RESP RATE	The displayed respiration rate value is below the set alert limit in the <b>SET ALERTS</b> screen (press <b>MENU</b> key, then select <b>SET ALERTS</b> to view the alert limit settings).	M
LOW SpO <sub>2</sub>	The displayed SpO <sub>2</sub> value is below the set alert limit in the <b>SET ALERTS</b> screen (press <b>MENU</b> key, then select <b>SET ALERTS</b> to view the alert limit settings).	H
MONITOR INOPERABLE AIRWAY ZERO ERROR	The NICO® monitor detected a problem with its pneumatic flow and pressure sub-system. Contact qualified personnel for monitor repair or exchange.	L
MONITOR INOPERABLE BARO PRESS ERROR	The NICO® monitor detected a problem with its internal barometric pressure sensor. Contact qualified personnel for monitor repair or exchange.	L
MONITOR INOPERABLE CLOCK FAILURE	The NICO® monitor detected a problem with its internal clock. Contact qualified personnel for monitor repair or exchange.	L
MONITOR INOPERABLE FLOW ZERO ERROR	The NICO® monitor detected a problem with its flow zeroing sub-system or related pneumatic components. Contact qualified personnel for monitor repair or exchange.	L
MONITOR INOPERABLE NICO VALVE ZERO ERR	The NICO® monitor detected a problem with its internal rebreathing valve control circuitry or related pneumatic components. Contact qualified personnel for monitor repair or exchange.	L
MONITOR INOPERABLE SpO <sub>2</sub> HDW ERROR	The NICO® monitor detected a problem with its pulse oximetry sub-system. Contact qualified personnel for monitor repair or exchange.	L
NO RESP: xx:xx	The time selected in the <b>SET ALERTS</b> screen for the NO RESP (no respiration) alert was exceeded since the end of the last detected breath (press <b>MENU</b> key, then select <b>SET ALERTS</b> to view the alert limit settings).	H
PULSE SEARCH	The pulse oximeter is not detecting a sufficient pulse. This could be due to: <ul style="list-style-type: none"> <li>• SpO<sub>2</sub> sensor is off of the patient</li> <li>• Insufficient perfusion at the site</li> <li>• Tissue at the site is too thick or too thin</li> </ul>	S
SpO <sub>2</sub> PROBE FAILURE	The pulse oximeter sensor is faulty. Replace the sensor and contact qualified service personnel.	M
SpO <sub>2</sub> PROBE?	<ul style="list-style-type: none"> <li>• The pulse oximeter sensor was not connected to the NICO® monitor when it was powered up.</li> <li>• (Flashing) SpO<sub>2</sub> sensor was disconnected from the monitor after it was powered up. Acknowledge by pressing the Silence key.</li> </ul>	S
WARMUP	The CAPNOSTAT® CO <sub>2</sub> sensor is not at proper operating temperature yet.	S



**C.O. Message Area**

The C.O. Message Area is dedicated to cardiac output related information and may be blank or contain a message.

The C.O. Message Area messages are listed below, in alphabetical order.

(Alert Class: H-High Priority, M-Medium Priority, L-Low Priority, S-Status Message. See "NICO® Alert Priorities" on page 56 for details.)

C.O. Message Area	Message Description	Alert Class
BLOOD GASES HAVE BEEN RESET	A NICO® cycle has started after 20 minutes of a no respiration timeout. Data not available when no breaths are detected 20 minutes after the last detected breath.	S
CO <sub>2</sub> UNSTABLE CO <sub>2</sub> STABILIZING	The NICO® monitor was not able to calculate a cardiac output value. This can be due to: <ul style="list-style-type: none"> <li>• Spontaneous breaths or efforts</li> <li>• Surgeon moving the lungs</li> <li>• Ventilator adjustments</li> </ul>	L
CONSIDER USING SMALL NICO SENSOR	Resizing the NICO Loop™ was not effective because the ventilator set tidal volume is less than 300 ml. The NICO® monitor is suggesting a different sized sensor, with smaller loop, to correct the condition.	L
CONSIDER USING STANDARD NICO SENSOR	If a small NICO Sensor™ is currently in use: Resizing the NICO Loop™ was not effective because the ventilator set tidal volume is greater than 500 ml. The NICO® monitor is suggesting a different sized sensor, with a larger loop, to correct the condition.  If a large NICO Sensor™ is currently in use: Resizing the NICO Loop™ was not effective because the ventilator set tidal volume is less than 1000 ml. The NICO® monitor is suggesting a different sized sensor, with a smaller loop, to correct the condition.	L
CONSIDER USING LARGE NICO SENSOR	Resizing the NICO Loop™ was not effective because the ventilator set tidal volume is greater than 1000 ml. The NICO® monitor is suggesting a different sized sensor, with a larger loop, to correct the condition.	L
EXPAND LOOP	The NICO Loop™ (expandable rebreathing volume on the NICO Sensor™) needs to be expanded. Expand the loop by approximately 3-6 inches or until the message is removed. Note that the message is displayed only during the rebreathing phase of the NICO® cycle. If the loop is not appropriately sized by the end of the rebreathing phase, the message will be removed and displayed again during the next rebreathing phase. If this message persists with maximal expansion of the NICO Loop™, the tidal volume may be too large for the ventilatory conditions for NICO® to report accurate results.	L
NEXT  : xx:xx	There are x:xx minutes:seconds until the beginning of the next rebreathing period (provided as an indicator as to the current state of the NICO® cycle).	S
NICO SENSOR?	The NICO Sensor™ has not been connected to the monitor since it was last turned on.	S

C.O. Message Area	Message Description	Alert Class
 REBREATHING	The patient is currently rebreathing a portion of his/her tidal volume in order for NICO® to calculate cardiac output (provided as an indicator of the current state of the NICO® cycle). The rebreathing phase of the NICO® cycle lasts for 50 seconds.	S
REBREATHING OFF	<p>Rebreathing and therefore C.O. measurements are currently disabled. The <b>STOP/CONTINUE REBREATHING</b> key is illuminated amber while rebreathing is off, and can be pressed to enable rebreathing and C.O. measurements. Rebreathing is off when:</p> <ul style="list-style-type: none"> <li>The monitor is first turned on until the <b>STOP/CONTINUE REBREATHING</b> key is pressed</li> <li>The <b>STOP/CONTINUE REBREATHING</b> key is pressed while C.O. measurements are enabled</li> <li>The monitor detected a system fault or condition which warrants automatic disabling of C.O. measurements</li> </ul>	S
REBREATHING OFF ADAPTER DISCONNECT REMOVE FROM CIRCUIT	The NICO Sensor™ was disconnected from the monitor after C.O. measurements had been made since the last power-up. The NICO Sensor™ should be removed from the breathing circuit in order to avoid leaking breathing circuit gas through the NICO Sensor™'s connector.	S
REBREATHING OFF LARGE NICO SENSOR IDENTIFIED	A large size NICO Sensor™ was just connected to the NICO® monitor.	S
REBREATHING OFF SMALL NICO SENSOR IDENTIFIED	A small size NICO Sensor™ was just connected to the NICO® monitor.	S
REBREATHING OFF STANDARD NICO SENSOR IDENTIFIED	A standard size NICO Sensor™ was just connected to the NICO® monitor.	S
REBREATHING OFF NICO SENSOR FAILURE	A problem with the NICO Sensor™ was detected by the monitor. Discard the sensor and replace it. If the problem persists, contact qualified service personnel.	M
REBREATHING OFF PRESS  KEY TO CONTINUE	Rebreathing and therefore C.O. measurements are currently disabled and can be enabled by pressing the <b>STOP / CONTINUE REBREATHING</b> key.	S
REBREATHING PAUSED WAITING FOR ETCO <sub>2</sub> < XX	Rebreathing and therefore C.O. measurements have been temporarily paused automatically by the monitor, and will resume automatically once the indicated parameter is within the stated range (here, XX = 85 mmHg, 11.5 kPa, 11.5 %).	L
REBREATHING PAUSED WAITING FOR ETCO <sub>2</sub> > XX	Rebreathing and therefore C.O. measurements have been temporarily paused automatically by the monitor, and will resume automatically once the indicated parameter is within the stated range (here, XX = 15 mmHg, 2.0 kPa, 2.0 %).	L
REBREATHING PAUSED WAITING FOR RR < 60 br/m	Rebreathing and therefore C.O. measurements have been temporarily paused automatically by the monitor, and will resume automatically once the indicated parameter is within the stated range.	L

C.O. Message Area	Message Description	Alert Class
REBREATHING PAUSED WAITING FOR RR > 3 br/m	Rebreathing and therefore C.O. measurements have been temporarily paused automatically by the monitor, and will resume automatically once the indicated parameter is within the stated range.	L
REBREATHING PAUSED WAITING FOR VCO <sub>2</sub> > 20 mL/min	Rebreathing and therefore C.O. measurements have been temporarily paused automatically by the monitor, and will resume automatically once the indicated parameter is within the stated range.	L
REBREATHING PAUSED WAITING FOR Vt > 200 mL	Rebreathing and therefore C.O. measurements have been temporarily paused automatically by the monitor, and will resume automatically once the indicated parameter is within the stated range.	L
RETRACT LOOP	The NICO Loop™ (expandable rebreathing volume on the NICO Sensor™) needs to be retracted (made smaller). Retract the loop by approximately 3-6 inches or until the message is removed. Note that the message is displayed only during the rebreathing phase of the NICO® cycle. If the loop is not appropriately sized by the end of the rebreathing phase, the message will be removed and displayed again during the next rebreathing phase. If this message persists with the NICO Loop™ at its minimal size, the tidal volume may be too small for the ventilatory conditions for NICO® to report accurate results.	L

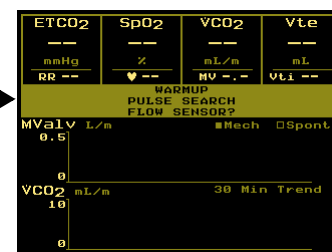
## Message Areas - Respiratory Mechanics mode

For Cardiac Output messages, see page 73.

In Respiratory Mechanics mode, the monitor uses one General Message Area to convey information to the user.

General Message Area

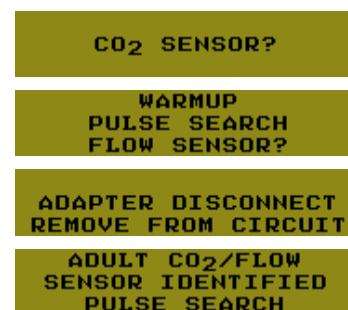
WARMUP  
PULSE SEARCH  
FLOW SENSOR?



### General Message Area

The General Message Area in Respiratory Mechanics mode displays all messages, including system status, alert, and error conditions. It may be blank or:

- contain 1, 2 or 3 single-line messages
- contain 1 multi-line message
- contain 1 multi-line message and 1 single-line message



The General Message Area messages are listed below, in alphabetical order.

(Alert Class: H-High Priority, M-Medium Priority, L-Low Priority, S-Status Message. See "NICO® Alert Priorities" on page 56 for details.

General Message Area	Message Description	Alert Class
ADAPTER DISCONNECT REMOVE FROM CIRCUIT	The CO <sub>2</sub> /Flow sensor is not connected to the NICO® monitor. The CO <sub>2</sub> /Flow sensor should be removed from the breathing circuit in order to avoid leaking breathing circuit gas through the sensor's connector.  NOTE: If a two-line message will not fit in the General Message Area because other higher priority messages are present, the message "FLOW SENSOR?" will be used for the same condition.	S
ADULT CO <sub>2</sub> /FLOW SENSOR IDENTIFIED	An adult size CO <sub>2</sub> /Flow sensor was just connected to the NICO® monitor.	S
ALERTS OFF	Displayed as a reminder that the default for all user selectable alerts is OFF. To cancel the message, adjust any individual limit value and activate the audible alert. Both the alert limit and audible alert must be activated.	S
AMBIENT LIGHT COVER SpO <sub>2</sub> PROBE	The monitor detects interference on the SpO <sub>2</sub> sensor from ambient light. This can be corrected by covering the SpO <sub>2</sub> sensor, or possibly by changing the sensor site.	S
CHECK / CHANGE AIRWAY ADAPTER	A change in the CO <sub>2</sub> adapter portion of the CO <sub>2</sub> /Flow sensor is detected. Possible causes: <ul style="list-style-type: none"> <li>• CAPNOSTAT® CO<sub>2</sub> sensor off adapter</li> <li>• High level of moisture and/or secretions in the adapter. Replace if needed.</li> </ul>	S
CO <sub>2</sub> SENSOR FAILURE REPLACE SENSOR	A problem with the CAPNOSTAT® CO <sub>2</sub> sensor has been identified. Replace the CAPNOSTAT® and return it to Novamatrix for exchange or repair.	M
CO <sub>2</sub> SENSOR?	The CAPNOSTAT® CO <sub>2</sub> sensor is not connected to the NICO® monitor.	S
CO <sub>2</sub> ZERO REQUIRED (MENU → SETUP)	The CAPNOSTAT® CO <sub>2</sub> sensor needs to be zeroed. Press the <b>MENU</b> key, then select <b>SETUP</b> , then <b>CO<sub>2</sub> ZERO NOW</b> , and follow the instructions on the screen. NOTE: the CO <sub>2</sub> adapter provided with the CAPNOSTAT® can be used for the CO <sub>2</sub> zero procedure rather than a new sensor.	S
DEMO MODE	The monitor is in demonstration mode and is not displaying patient data (all data is simulated). To exit demo mode, turn the monitor off, then back on.	S
ETCO <sub>2</sub> > XX mmHg	End tidal CO <sub>2</sub> is greater than 60 mmHg or exceeds the high alert limit. Appears in the general message area to supplement screens that do not display the ETCO <sub>2</sub> value.	L
FLOW SENSOR?	The CO <sub>2</sub> /Flow sensor is disconnected.  NOTE: This message may also be used in place of ADAPTER DISCONNECT REMOVE FROM CIRCUIT, when a two-line message will not fit in the General Message Area.	S
HIGH ETCO <sub>2</sub>	The displayed ETCO <sub>2</sub> value is above the set alert limit in the <b>SET ALERTS</b> screen (press <b>MENU</b> key, then select <b>SET ALERTS</b> to view the alert limit settings).	H
HIGH PIP	The displayed PIP value is above the set alert limit in the <b>SET ALERTS</b> screen (press <b>MENU</b> key, then select <b>SET ALERTS</b> to view the alert limit settings).	M

General Message Area	Message Description	Alert Class
HIGH PULSE	The displayed pulse rate value is above the set alert limit in the <b>SET ALERTS</b> screen (press <b>MENU</b> key, then select <b>SET ALERTS</b> to view the alert limit settings).	M
HIGH RESP RATE	The displayed respiration rate value is above the set alert limit in the <b>SET ALERTS</b> screen (press <b>MENU</b> key, then select <b>SET ALERTS</b> to view the alert limit settings).	M
HIGH SpO <sub>2</sub>	The displayed SpO <sub>2</sub> value is above the set alert limit in the <b>SET ALERTS</b> screen (press <b>MENU</b> key, then select <b>SET ALERTS</b> to view the alert limit settings).	M
INCOMPATIBLE CO <sub>2</sub> SENSOR	The wrong part number CAPNOSTAT® is connected to the NICO® monitor. Use only a CAPNOSTAT® with part number 9567-00 (this can be distinguished from other CAPNOSTAT® part numbers by the yellow part number label on the CAPNOSTAT®'s electrical connector).	M
INCOMPATIBLE FLOW SENSOR	The wrong flow sensor is connected to the NICO® monitor. Use only a NICO® CO <sub>2</sub> /Flow sensor part number 9765-00, 9766-00, or 9767-00. If message persists, a hardware error may exist. Contact qualified personnel for monitor repair or exchange.	M
INSP CO <sub>2</sub> : xx	(where xx is a numeric value with units of mmHg, kPa, or %). At least 3 mmHg, 0.1% or 0.1 kPa of CO <sub>2</sub> has been detected during inspiration (other than during rebreathing) for at least ten continuous seconds.	S
LOW ETCO <sub>2</sub>	The displayed ETCO <sub>2</sub> value is below the set alert limit in the <b>SET ALERTS</b> screen (press <b>MENU</b> key, then select <b>SET ALERTS</b> to view the alert limit settings).	M
LOW PULSE	The displayed pulse rate value is below the set alert limit in the <b>SET ALERTS</b> screen (press <b>MENU</b> key, then select <b>SET ALERTS</b> to view the alert limit settings).	H
LOW RESP RATE	The displayed respiration rate value is below the set alert limit in the <b>SET ALERTS</b> screen (press <b>MENU</b> key, then select <b>SET ALERTS</b> to view the alert limit settings).	M
LOW SpO <sub>2</sub>	The displayed SpO <sub>2</sub> value is below the set alert limit in the <b>SET ALERTS</b> screen (press <b>MENU</b> key, then select <b>SET ALERTS</b> to view the alert limit settings).	H
MONITOR INOPERABLE AIRWAY ZERO ERROR	The NICO® monitor detected a problem with its pneumatic flow and pressure sub-system. Contact qualified personnel for monitor repair or exchange.	L
MONITOR INOPERABLE BARO PRESS ERROR	The NICO® monitor detected a problem with its internal barometric pressure sensor. Contact qualified personnel for monitor repair or exchange.	L
MONITOR INOPERABLE CLOCK FAILURE	The NICO® monitor detected a problem with its internal clock. Contact qualified personnel for monitor repair or exchange.	L
MONITOR INOPERABLE FLOW ZERO ERROR	The NICO® monitor detected a problem with its flow zeroing sub-system or related pneumatic components. Contact qualified personnel for monitor repair or exchange.	L
MONITOR INOPERABLE SpO <sub>2</sub> HDW ERROR	The NICO® monitor detected a problem with its pulse oximetry sub-system. Contact qualified personnel for monitor repair or exchange.	L
NEONATAL CO <sub>2</sub> /FLOW SENSOR IDENTIFIED	A neonatal size CO <sub>2</sub> /Flow sensor was just connected to the NICO® monitor.	S



General Message Area	Message Description	Alert Class
NO RESP: xx:xx	The time selected in the <b>SET ALERTS</b> screen for the NO RESP (no respiration) alert was exceeded since the end of the last detected breath (press <b>MENU</b> key, then select <b>SET ALERTS</b> to view the alert limit settings).	H
PEDIATRIC CO <sub>2</sub> /FLOW SENSOR IDENTIFIED	A pediatric size CO <sub>2</sub> /Flow sensor was just connected to the NICO <sup>®</sup> monitor.	S
PULSE SEARCH	The pulse oximeter is not detecting a sufficient pulse. This could be due to: <ul style="list-style-type: none"> <li>• SpO<sub>2</sub> sensor is off of the patient</li> <li>• Insufficient perfusion at the site</li> <li>• Tissue at the site is too thick or too thin</li> </ul>	S
SpO <sub>2</sub> PROBE FAILURE	The pulse oximeter sensor is faulty. Replace the sensor and contact qualified service personnel.	M
SpO <sub>2</sub> PROBE?	<ul style="list-style-type: none"> <li>• The pulse oximeter sensor was not connected to the NICO<sup>®</sup> monitor when it was powered up.</li> <li>• (Flashing) SpO<sub>2</sub> sensor was disconnected from the monitor after it was powered up. Acknowledge by pressing the Silence key.</li> </ul>	S
WARMUP	The CAPNOSTAT <sup>®</sup> CO <sub>2</sub> sensor is not at proper operating temperature yet.	S



## External Devices

### GE Medical Systems Solar® Interface

The Solar® monitor from GE Medical Systems Information Technologies (GEMS-IT), connects to the NICO® via an Octanet and a DIDCA™ interface adapter.

Solar® interface software is compatible with NICO® release 2.1 or above. If your NICO® software is updated, please complete and fax the software notification found in your GEMS-IT service manual, so they can confirm continued compatibility.

#### Preparing for Use

To setup and connect the NICO® monitor to the GEMS-IT Solar® monitor, you will need the following:

- NICO® monitor with software revision 3.1 or greater
- GEMS-IT Solar® monitor, Model 7000, or 8000 with software version V6A or higher, or GEMS-IT Solar® monitor, Model 8000M with software version V1A or higher
- GEMS-IT Octanet module, (PN: OCTANET=A)
- DIDCA™ interface adapter, (PN: 420915-058)
- GEMS-IT Octanet cable (PN: 418335-00x). Cables come in various lengths and are available from GEMS-IT.
- GEMS-IT Solar® monitor cable (PN: 409752-00x or 700520-00x)
- Optional: GEMS-IT TRAM-Net Hub (PN: 410217-001) and TRAM-Net cable (PN: 409752-00x). Instructions for use of the TRAM-Net are detailed within Octanet and other service documents provided by GEMS-IT.

NOTE: All GEMS-IT parts are supplied by GEMS-IT.

#### Component Setup

Refer to the following steps for correct cable connections.

- 1 Connect the DIDCA™ interface adapter to the connector labeled RS232 1 on the back of the NICO®. The interface adapter is programmed specifically to work with a NICO® monitor.
- 2 Connect the Octanet cable between the interface adapter and one of the eight Octanet serial ports.
- 3 Connect the Solar monitor cable (PN: 409752-00x for Models 7000 and 8000, PN: 700752-00x for model 8000M) from the Octanet to the Solar® monitor

Complete the communication cabling by referring to the power up instructions found in the Octanet Connectivity Device Service Manual (PN: 418264-003).

- 4 Ensure Octanet serial port LED is steady green.

#### Transmitted Parameters

The following parameters are transmitted from the NICO® monitor to the Solar® monitor.

- The CO, CI, SV, CO confidence level and PCBF values will be displayed in the NICO parameter block.
- Four of the following sub parameters can be displayed in the RM parameter block: PEF, MV, MVs, MVm, TV, TVs, TVm, PIP, MAWP, PEEP, RR, RRs, RRm, I:E, CYDN, RAWe.

- The CO<sub>2</sub> inspired, CO<sub>2</sub> expired, and respiration rate (RR) values will be displayed in the CO<sub>2</sub> parameter block.
- The SPO<sub>2</sub> value and pulse rate (RATE) value will be displayed in the SPO<sub>2</sub> parameter block.

## Agilent Technologies VueLink Interface

The NICO® interface to the Agilent Technologies<sup>1</sup> VueLink module provides a pathway for NICO® data to be viewed on the Agilent Technologies Patient Monitoring System. The data from NICO® is available for display in conjunction with the other parameters configured for display on the Agilent Technologies Patient Monitor.

### Preparing for Use

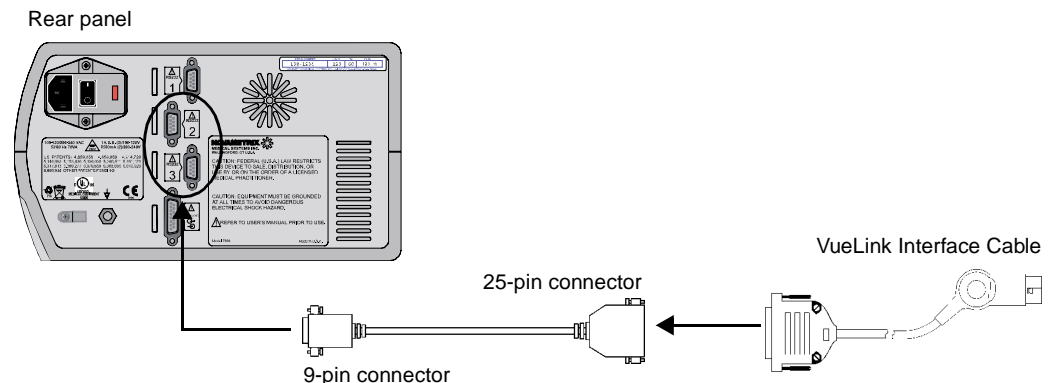
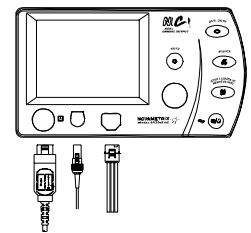
To setup and connect the NICO® monitor to the Agilent VueLink module, you will need the following:

- NICO® monitor with software revision 3.1 or greater.
- Agilent Patient Monitor with software revision C (9.xx) or higher.
- Agilent VueLink module, Auxiliary Plus B with Open Interface (product number M1032 option A05).
- Agilent 4-meter VueLink Interface Cable (part number K6B)
- 25-pin female to 9-pin male null modem (crossover) cable

NOTE: The Agilent Patient Monitor, VueLink Module and Agilent interface cable are supplied by Agilent.

### Component Setup

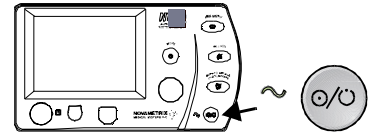
- 1 Connect the CAPNOSTAT® CO<sub>2</sub> sensor, flow sensor, pulse oximeter probe and AC power cord to the NICO® monitor.
- 2 Connect the 25-pin male connector on the VueLink Interface Cable to the 25-pin female connector on the null modem cable, then connect the 9-pin male connector to the rear panel of the NICO®. Tighten screws.
- 3 Connect the other end of the VueLink cable to the VueLink module by grasping the end of the connector and pushing it into the receptacle on the VueLink module.
- 4 Plug the VueLink Module into an available slot in the Agilent monitoring system module rack.
  - The VueLink module may be stored in the rack when not in use.



1. Agilent Technologies was formerly Hewlett-Packard. The information above also applies to existing HP products.

- 1 Press the **Operate/Standby** key to turn the monitor on and off.

- NICO® can operate from its internal battery or from the AC Mains. (See “AC/Battery Operation” on page 4 for details.)



- 2 Press the **MENU** key to activate **SELECT A SCREEN**. The key's green icon illuminates.

- Press the key again to return to the previously displayed screen.

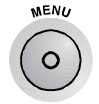
- 3 Highlight and then select **SETUP** by turning and then pressing the **KNOB**.

- 4 The **SETUP** screen is displayed.

- 5 Turn and press the **KNOB** to select **INPUT/OUTPUT**.

- 6 Turn and press the **KNOB** to select **RS232-2** or **RS232-3**.

- 7 Turn and press the **KNOB** to select **VUELINK**.



NOTE: If you need detailed installation and operating instructions for the Agilent VueLink Module and the Agilent Patient Monitor, refer to the Agilent Operator's Manual.

### Transmitted Parameters

A total of twenty-four parameters are transmitted to the Agilent Patient Monitor. The parameter selection varies depending upon whether you are in Cardiac Output mode or Respiratory Mechanics mode. Seventeen of these parameters will display in the Agilent Main Screen, a maximum of six at a time. Seven parameters display in the Task Window only.

Label	Parameter	Units
AWRR	Respiratory Rate	rpm
Cdyn	Dynamic Compliance	ml/cmH <sub>2</sub> O
RAW e	Expired Airway Resistance (Dynamic)	cmH <sub>2</sub> O/L/S
PIP	Peak Inspiratory Pressure	cmH <sub>2</sub> O
PEEP	Positive End Expiratory Pressure	cmH <sub>2</sub> O
Pmean	Mean Airway Pressure	cmH <sub>2</sub> O
Pulse	Pulse Rate	bpm
SpO <sub>2</sub>	SpO <sub>2</sub>	%
ETCO <sub>2</sub>	ETCO <sub>2</sub>	*mmHg, %, kPa
PECO <sub>2</sub>	Mixed Expired CO <sub>2</sub>	*mmHg, %, kPa
PEF	Peak Expiratory Flow	L/min
TVin	Inspired Tidal Volume	ml
TVex	Expired Tidal Volume	ml
MV t	Total Minute Volume	L
MV s	Spontaneous Minute Volume	L
MV m	Mechanical Minute Volume	L
VCO <sub>2</sub>	CO <sub>2</sub> Elimination	ml/min
VD aw	Airway Deadspace	ml
Respiratory Mechanics Mode only:		
RAW i	Inspired Airway Resistance (Dynamic)	cmH <sub>2</sub> O/L/S
VT alv t	Total Alveolar Tidal Volume	ml

VT alv s	Spontaneous Alveolar Tidal Volume	ml
VT alv m	Mechanical Alveolar Tidal Volume	ml
MV alv	Alveolar Minute Volume (Total)	L
VdVtPh	Physiologic deadspace to tidal volume ratio	
Cardiac Output Mode only:		
CO-a	Average Cardiac Output	L/min
CO-f	Fast-mode Cardiac Output	L/min
CI	Cardiac Index	L/min/m <sup>2</sup>
PCBF	Pulmonary Capillary Blood Flow	L/min
SV	Stroke Volume	ml
SVR	Systemic Vascular Resistance	dynes sec/cm <sup>5</sup>

\*CO<sub>2</sub> parameters are reported in either mmHg, kPa, or %, depending upon the CO<sub>2</sub> units currently selected for the NICO® monitor.

### Transmitted Waveforms

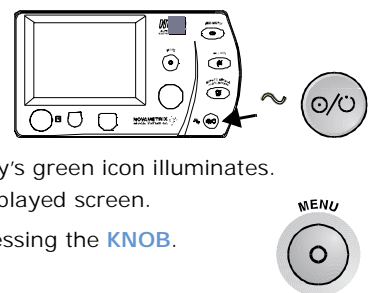
A total of five waveform are transmitted to the Agilent Patient Monitor; a maximum of two may viewed at one time.

Label	Waveform	Units
AWF	Airway Flow	L
AWP	Airway Pressure	cmH <sub>2</sub> O
CO <sub>2</sub>	CO <sub>2</sub> Capnogram	mmHg, %, kPa
PLETH	Plethysmogram	N/A
AWV	Volume	ml

## ASCII Output

The NICO® monitor must be set to the appropriate interface.

- 1 Press the **Operate/Standby** key to turn the monitor on and off.
  - NICO® can operate from its internal battery or from the AC Mains. (See "AC/Battery Operation" on page 4 for details.)
- 2 Press the **MENU** key to activate **SELECT A SCREEN**. The key's green icon illuminates.
  - Press the key again to return to the previously displayed screen.
- 3 Highlight and then select **SETUP** by turning and then pressing the **KNOB**.
- 4 The **SETUP** screen is displayed.
- 5 Turn and press the **KNOB** to select **INPUT/OUTPUT**.
- 6 Turn and press the **KNOB** to select **RS232-2** or **RS232-3**.
- 7 Turn and press the **KNOB** to select:
  - **ASCII OUTPUT** to a serial printer
  - **ASCII OUTPUT 2** for data collection using a PC
- 8 Connect the device to the appropriate rear panel connector.



*Analog Output***Output to a Serial Printer**

For output to a serial printer such a strip chart recorder or the Seiko DPU-414 printer, configure your serial printer to 9600 bps, no parity, 8 data bits, 1 stop bit.

An output sample is shown below:

JUL 6, 2000	9:47:14			
C.O.	C.I.	S.V.	C.O.-f	PCBF
5.2	2.8	69	5.2	4.9
VCO2	MV	Mvalv	Vti	Vte
0	0.0	0.0	0	0
PIP	MAP	PEEP	Cdyn	Raw
23	9	4	27	15
ETCO2	RR	SpO2	PR	
33.9	15	97	75	

**Output files for use on a PC**

When configured to **ASCII OUTPUT 2**, NICO® will output a text file that can be imported into a spreadsheet program such as Microsoft Excel. Configure your serial device to 19200 bps, no parity, 8 data bits, 1 stop bit.

Data is output once every breath. An output sample is shown below:

10:40:04, PR=75, SPO2=97, RR=20, C.O.=0.0, C.O.-f=0.0, CI=0.0, SV=0, VCO2=429, ETCO2=39, PECO2=32, MV=12.2, MVALV=11.0, Vti=916, Vte=907, Vtalv=546, VdAW=63, PIP=45, MAP=22, PEEP=9, Cdyn=27, Raw=13

**Analog Output**

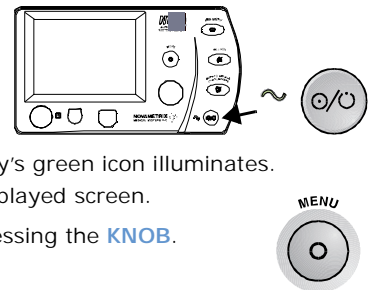
NICO® directly supports interface to analog devices.

**Setup**

The NICO® monitor must be set to the appropriate interface.

- 1 Press the **Operate/Standby** key to turn the monitor on and off.
  - NICO® can operate from its internal battery or from the AC Mains. (See "AC/Battery Operation" on page 4 for details.)
- 2 Press the **MENU** key to activate **SELECT A SCREEN**. The key's green icon illuminates.
  - Press the key again to return to the previously displayed screen.
- 3 Highlight and then select **SETUP** by turning and then pressing the **Knob**.
- 4 The **SETUP** screen is displayed.
- 5 Turn and press the **Knob** to select **INPUT/OUTPUT**.
- 6 Turn and press the **Knob** to select **ANALOG OUT 1-4**.
- 7 Turn and press the **Knob** to select the parameters you want from **ANALOG OUT 1-4** (maximum of 1 per), to be transmitted to an analog device like a strip chart recorder, etc.
 

CO, CI, SV, PCBF, ETCO<sub>2</sub>, SpO<sub>2</sub>, resp rate, and pulse rate value outputs are available, as well as CO<sub>2</sub>, plethysmogram, flow, and airway pressure waveform data.
- 8 Calibrate the recorder to the correct voltage levels using the **ANALOG CAL.** setting. Press **ZERO**, **HALF** and **FULL** to set the analog outputs.
  - **ZERO** — 0 volts
  - **HALF** — 0.50 volts
  - **FULL** — 1.00 volts



### Ranges and Units

- Analog Input/Output Port (selectable, 0 to 1 volt range):
  - C.O. - Cardiac Output, 0-20 L/m, 50mV/L/m
  - CI - Cardiac Index, 0-20 L/m, 50mV/L/m
  - SV - Stroke Volume, 0-20 L/m, 50mV/L/m
  - PCBF - 0-20 L/m, 50 mV/L/m
  - ETCO<sub>2</sub> - 0-150 mmHg, 0-20 kPa or %, 6.67mV/mmHg
  - SpO<sub>2</sub> - 0-100%, 10mV/%
  - Resp Rate - 0-150 br/min, 6.67mV/br/min
  - Pulse Rate - 0-250 bpm, 4mV/bpm
  - CO<sub>2</sub> Waveform - 0-150 mmHg, 0-20 kPa or %, 6.67mV/mmHg
  - Pleth Waveform - auto scaled
  - Flow Waveform - -125 to +125 L/m, 4mV/L/m
  - Airway Pressure Waveform - -20 to +105 cmH<sub>2</sub>O, 8mV/cmH<sub>2</sub>O

Pin#	Description	Pin #	Description
1	Ground	9	Ground
2	Channel 1 - input (not enabled)	10	Ground
3	Channel 2 - input (not enabled)	11	Channel 1 - output
4	Channel 3 - input (not enabled)	12	Channel 2 - output
5	Channel 4 - input (not enabled)	13	Channel 3 - output
6	Ground	14	Channel 4 - output
7	Ground	15	Input/Output Sense
8	Ground		

### Alerts and Messages

Alarms and messages are not transmitted from the NICO<sup>®</sup> monitor to the Agilent VueLink module; most alarms and messages are not transmitted from the NICO<sup>®</sup> monitor to the GEMS-IT Solar<sup>®</sup> monitor. All alarms and messages should be viewed directly from the NICO<sup>®</sup> monitor.



## Maintenance

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This section details routine maintenance procedures for the NICO® monitor, its sensors and accessories.

### Cleaning and Sterilization

To clean and/or sterilize the monitor and its accessories:

#### *Single Patient Use NICO Sensor™*

- Treat the NICO Sensor™ in accordance with hospital protocol for single-patient use items.

#### *CO<sub>2</sub>/Flow Sensors*

- Treat CO<sub>2</sub>/Flow sensors in accordance with hospital protocol for single-patient use items.

#### *CAPNOSTAT® CO<sub>2</sub> Sensor*

- Do not immerse the sensor. Do not sterilize the sensor.
- The sensor can be cleaned and disinfected by wiping with solutions such as a 70% isopropyl alcohol, 2% glutaraldehyde, or 10% bleach solution. Then wipe down with a water dampened clean cloth to rinse. Dry before use.
- Make certain that the sensor windows are clean and dry before reuse.

#### *NICO® Monitor*

- Do not immerse the monitor. Do not sterilize the monitor.
- Turn the monitor off and unplug from the AC power source before cleaning.
- The monitor can be cleaned and disinfected by wiping with solutions such as a 70% isopropyl alcohol, 2% glutaraldehyde, or 10% bleach solution. Then wipe down with a water dampened clean cloth to rinse. Dry before use.

#### *SpO<sub>2</sub> Finger Sensor*

- Do not immerse the finger sensor. Do not sterilize the finger sensor.
- The sensor can be cleaned and disinfected by wiping with solutions such as a 70% isopropyl alcohol, 2% glutaraldehyde, or 10% bleach solution. Then wipe down with a water dampened clean cloth to rinse. Dry before use.
- Make certain that the finger sensor windows are clean and dry before reuse.
- After cleaning the finger sensor, perform a Quick Check to verify the sensor is functional (See “Sensor Quick Check” on page 68).

#### *SpO<sub>2</sub> Y-Sensor™*

- The Y-Sensor™ may be immersed up to—but not including—the connector, in a 2% glutaraldehyde solution, or 10% bleach solution. Refer to manufacturer’s instructions and standard hospital protocols to determine recommended times for disinfection and sterilization.
- Rinse thoroughly with water and dry before use. (Do not rinse the connector).
- After cleaning or sterilizing the Y-Sensor™, perform a Quick Check to verify the sensor is functional (See “Sensor Quick Check” on page 68).

#### *SpO<sub>2</sub> Tapes and Foam Wraps*

- Treat tapes and foam wraps in accordance with hospital protocol for single-patient use items.



### Ear Clip

- Clean with a cloth dampened with 70% isopropyl alcohol. After cleaning, thoroughly wipe the ear clip with a clean, water dampened cloth.

## Monitor Maintenance Schedules

The NICO® monitor performs a diagnostic self-test at powerup that checks the internal electronics. If this self test fails, the normal monitoring display will not appear. Remove the NICO® monitor from use and contact qualified service personnel.

The NICO® monitor should undergo inspection and safety checks on a regular basis or according to institutional protocol. A Service Manual (Catalog No. 9226-90) containing information to assist qualified service personnel is available.

## Battery Maintenance

The monitor may not power up on battery power if the battery is not sufficiently charged. If the NICO® monitor has not been used or powered by the AC Mains for an extended time—3 months or more—allow the battery to charge for 12 hours before use. (The internal battery may slowly discharge over long periods of non-use.)

To charge the battery, connect the line cord to an AC source and set the rear panel power switch ON (I). Check that the AC Mains Power Indicator on the front panel is illuminated (green). Allow the battery to charge for 12 hours. (Refer battery replacement to qualified service personnel.)



## Specifications

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### General

Specifications for the Novamatrix NICO® Monitor, Model 7300, are listed for informational purposes only, and are subject to change without notice.

### Cardiac Output

- Measurement Frequency: Rebreathing cardiac output measurement made every three minutes, rebreathing period is 50 seconds.
- Cardiac Output Range: 0.5-19.9 liters/minute
- Cardiac Output Resolution: 0.1 liters/minute
- Pulmonary Capillary Blood Flow (PCBF) Range: 0.5-19.9 L/min, Resolution: 0.1 L/min
- Cardiac Index Range: 0-9.9 L/min/meter<sup>2</sup>, Resolution: 0.1 L/min/meter<sup>2</sup>
- Stroke Volume Range: 0-250 ml, Resolution: 1 ml
- Rebreathing Valve/sensor:
  - Valve type: dual diaphragm, pneumatically controlled
  - Return spring: automatically returns valve to normal position
  - Resistance: 3 cmH<sub>2</sub>O/L/min maximum
  - Rebreathed volume: normal position 35 ml; rebreathing position 150-450 ml (std.)
  - CO<sub>2</sub>/flow sensor: integrated into valve assembly
- Parameter limits for NICO® measurements:
  - VCO<sub>2</sub>: >20 ml/min
  - RR: >3, <60
  - Vt: >200 (small and standard), >400 (large)
  - ET-CO<sub>2</sub>: >15, <85 mmHg (<100 mmHg during rebreathing)  
>2.0, <11.5 kPa or % (<13.5 kPa or % during rebreathing)

### CO<sub>2</sub>

- Principle of Operation: Non-Dispersive Infrared (NDIR) absorption, dual wavelength ratio-metric-single beam optics, mainstream sensor.
- Response Time: Less than 60 ms
- Gas composition effects: Operator selectable
- CAPNOSTAT® CO<sub>2</sub> Sensor:
  - Weight: Less than 18 g without cable
  - Sensor Size: 1.3 x 1.67 x .85 inches (3.3 x 4.2 x 2.2 cm), 8 foot cable (2.44 m)
  - Construction: Durable high performance plastic, ultra-flexible cable. Shock Resistant: Sensor will withstand a 6 foot drop to a tile floor.
- End Tidal CO<sub>2</sub>:
  - Range: 0-150 mmHg, 0-20 kPa or % at Pb 760 mmHg
  - Accuracy: ± 2 mmHg for 0-40 mmHg, ± 5% of reading for 41-70 mmHg, ± 8% of reading for 71-150 mmHg
- Respiratory Rate:
  - Range: 2-150 breaths/min
  - Accuracy: ± 1 breath/min

### Flow

- Flow Range (L/min) at Pb 760 mmHg, room air, 35°C
  - Adult: 2 to 180
  - Pediatric: .5 to 100
  - Neonatal: .25 to 25
- Flow Accuracy: Greater of ± 3% reading or:
  - Adult: .5 L/min
  - Pediatric: .25 L/min
  - Neonatal: .125 L/min
- Tidal Volume Range (ml)
  - Adult: 200 to 3000
  - Pediatric: 30-400

- Neonatal: 1-100
- Airway Pressure Range (cmH<sub>2</sub>O):  $\pm 120$
- Accuracy: greater of 0.5 cmH<sub>2</sub>O or  $\pm 2\%$  reading

## SpO<sub>2</sub>

- Oxygen Saturation
  - Range: 0-100%
  - Accuracy:  $\pm 2\%$  for 80-100% (for 1 standard deviation or approximately 68% of readings), unspecified for 0-79%
  - Averaging Time: 2 seconds
- Pulse Rate:
  - Range: 30-250 beats per minute
  - Accuracy:  $\pm 1\%$  of full scale (for 1 standard deviation or approximately 68% of readings)
  - Averaging Time: 8 seconds

## Monitor Specifications

- Classification (IEC601-1): Class I/internal power source, type BF, continuous operating mode, enclosure protection rating IPX0.
- Operating Environment: 50-95° F (10-35° C), 0-90% relative humidity (non-condensing)
- Size: Height 6.5 in., Width 10.75 in., Depth 9.5 in.
- Weight: 9 lbs, 6 oz.
- Power: 100-240 VAC, 50-60 Hz, 70VA
- Fuse Rating: 100-240 VAC, 0.5 A 250 V Slo-Blo (x2); 200-240 VAC, T 250 mA/250 V (x2)
- Battery: Internal, Sealed lead-acid gel-cell, 45 minute life on full charge (on-screen life indicator), 12 hours recharge time.
- Display: 4.625 x 3.5 inch EL, 320x240 pixels
- Electromagnetic Emissions: Conforms to EMC Directive 89/336/EEC, CISPR Class A. Tested to EN55011 (1991) and CISPR11 (1990).
- Electromagnetic Immunity: Conforms to EMC Directive 89/336/EEC, EN50082-1 (1992). Tested to IEC801-3 (1984) Radiated Immunity. Conforms to Medical Device Directive 93/42/EEC EN60601-1 (1992). Tested to IEC801-2 (1991) ESD, IEC801-4 (1988) EFT, and IEC1000-4-5 (1995) Surge Immunity.

## RS232 Communications

- RS232 Communications Ports:

Pin #	RS232-1	RS232-2	RS232-3
2	Rx	Rx	Rx
3	Tx	Tx	Tx
5	Ground	Ground	Ground
7	n/a	RTSB	n/a
8	n/a	CTSB	n/a
9	n/a	Power	n/a



## NICO<sup>®</sup> Accessories

Catalog No.	Description
9226-00	<b>NICO<sup>®</sup> Non-Invasive Cardiac Output Monitor</b> , Model 7300 Includes: Monitor, CAPNOSTAT <sup>®</sup> CO <sub>2</sub> Sensor, SpO <sub>2</sub> Sensor, Power Cord and User's Manual. Warranty for NICO <sup>®</sup> Monitor and CAPNOSTAT <sup>®</sup> CO <sub>2</sub> Sensor is 2 years.
8950-00	<b>NICO Sensor<sup>™</sup></b> (10 per box) <b>Small size (for tidal volumes of 200 - 500 mL)</b>
8951-00	<b>NICO Sensor<sup>™</sup></b> (10 per box) <b>Standard size (for tidal volumes of 400 - 1000 mL)</b>
8952-00	<b>NICO Sensor<sup>™</sup></b> (10 per box) <b>Large size (for tidal volumes of 750 - 1500 mL)</b>
9567-00	<b>CAPNOSTAT<sup>®</sup> CO<sub>2</sub> Sensor - NICO</b>
6934-00	<b>Cable Management Straps</b> for use with the CAPNOSTAT <sup>®</sup> CO <sub>2</sub> Sensor. Organizes and holds multiple cables and tubings (package of 5)
8751-00	<b>CAPNOSTAT<sup>®</sup> CO<sub>2</sub> Sensor Cable Holding Clips</b> (50 per box)
8776-00	<b>SuperBright<sup>™</sup> Finger Sensor</b> (10 ft. sensor cable) 1 yr. warranty
8791-00	<b>SuperBright<sup>™</sup> Y-Sensor</b> (10 ft. sensor cable) 90 day warranty
9765-00	<b>NICO<sup>®</sup> CO<sub>2</sub>/Flow Sensors</b> (10 per box) <b>Neonatal size</b>
9766-00	<b>NICO<sup>®</sup> CO<sub>2</sub>/Flow Sensors</b> (10 per box) <b>Pediatric size</b>
9767-00	<b>NICO<sup>®</sup> CO<sub>2</sub>/Flow Sensors</b> (10 per box) <b>Adult size</b>
6063-01	<b>Single Patient Use Airway Adapter</b> - (1 piece) Adult size
6455-00	<b>Single Patient Use SpO<sub>2</sub> Sensor (10 per box) Pediatric/Adult</b>
6455-25	<b>Single Patient Use SpO<sub>2</sub> Sensor (25 per box) Pediatric/Adult</b>
6480-00	<b>Single Patient Use SpO<sub>2</sub> Sensor (10 per box) Neonatal/Pediatric</b>
6480-25	<b>Single Patient Use SpO<sub>2</sub> Sensor (25 per box) Neonatal/Pediatric</b>
4941-00	<b>Saturation Sensor Extension Cable</b> (4 feet)
4942-00	<b>Saturation Sensor Extension Cable</b> (6 feet)
4943-00	<b>Saturation Sensor Extension Cable</b> (10 feet)
5266-00	<b>Saturation Sensor Extension Cable</b> (25 feet)
6147-00	<b>Saturation Sensor Extension Cable</b> (50 feet)
8828-00	<b>20mm Wrap Style Y-Strip Taping System</b> (100 per box) Neonatal foot and hand, pediatric toe or finger, color coded blue
8829-00	<b>25mm Wrap Style Y-Strip Taping System</b> (100 per box) Neonatal foot and hand, color coded green
8831-00	<b>20mm Finger Style Taping System</b> (100 per box) Use on pediatric finger or on small adult finger, color coded blue
8832-00	<b>25mm Finger Style Taping System</b> (100 per box) Use on adult finger, color coded green
6929-00	<b>Adhesive Foam Wraps</b> , Large (25 per box)
6968-00	<b>Adhesive Foam Wraps</b> , Small (25 per box)
8836-00	<b>Non-Adhesive Foam Wraps</b> , Large (25 per box)
8943-00	<b>Non-Adhesive Foam Wraps</b> , Small (25 per box)
6131-50	<b>Ear Clips</b> (5 per box)
6131-25	<b>Ear Clips</b> (25 per box)
8700-00	<b>Adhesive Dots</b> (200 per box)

Catalog No.	Description
9861-00	<b>Flow Connector Cap</b> , 3 port (25 per bag)
601012	<b>NICO</b> <sup>®</sup> 9-pin to 9-pin null modem (crossover) cable
600026	<b>Power Cord</b> (included with monitor)
9226-23	<b>NICO</b> <sup>®</sup> User Manual
9226-90	<b>NICO</b> <sup>®</sup> Service Manual



## Warranty

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Equipment manufactured or distributed by Novamatrix Medical Systems Inc., is fully guaranteed, covering materials and workmanship, for a period of one year from the date of shipment, except for certain disposable products and products with stated guarantees other than one year. Novamatrix reserves the right to perform guarantee service(s) at its factory, at an authorized repair station, or at the customer's installation.

Novamatrix' obligations under this guarantee are limited to repairs, or at Novamatrix' option, replacement of any defective parts of our equipment, except fuses, batteries, and calibration gasses, without charge, if said defects occur during normal service.

Claims for damages during shipment must be filed promptly with the transportation company. All correspondence concerning the equipment must specify both the model name and number, and the serial number as it appears on the equipment.

Improper use, mishandling, tampering with, or operation of the equipment without following specific operating instructions will void this guarantee and release Novamatrix from any further guarantee obligations.

### Service Department

For factory repair service:  
Call toll free: 1-800-243-3444  
To Call Direct: (203) 265-7701  
Facsimile (203) 284-0753  
<http://www.novamatrix.com>  
[techline@novamatrix.com](mailto:techline@novamatrix.com)

**Caution:** Federal (U.S.A.) law restricts this device to sale, distribution, or use by or on the order of a licensed medical practitioner.

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# **EXHIBIT 4**

# A New Family of Sensors for Pulse Oximetry

This new family of reusable sensors for noninvasive arterial oxygen saturation measurements is designed to cover all application areas. It consists of four sensors: adult, pediatric, neonatal, and ear clip.

**by Siegfried Kästle, Friedemann Nolle, Siegfried Falk, Anton Bukta, Eberhard Mayer and Dietmar Miller**

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Since the early 1980s, when pulse oximetry was introduced, this noninvasive method of monitoring the arterial oxygen saturation level in a patient's blood ( $\text{SpO}_2$ ) has become a standard method in the clinical environment because of its simple application and the high value of the information it gives nurses and doctors. It is as common in patient monitoring to measure the oxygen level in the blood as it is to monitor heart activity with the ECG. In some application areas, like anesthesia in a surgical procedure, it is mandatory for doctors to measure this vital parameter. Its importance is obvious considering that a human being cannot survive more than five minutes without oxygen supply to the brain.

Before the advent of pulse oximetry, the common practice was to draw blood from patients and analyze the samples at regular intervals—several times a day, or even several times an hour—using large hospital laboratory equipment. These in-vitro analysis instruments were either blood gas analyzers or hemoximeters. Blood gas analyzers determine the partial pressure of oxygen in the blood ( $\text{pO}_2$ ) by means of chemical sensors. Hemoximeters work on spectrometric principles and directly measure the ratio of the oxygenated hemoglobin to the total hemoglobin in a sample of blood ( $\text{SaO}_2$ ).

HP pioneered the first in-vivo technology to measure a patient's oxygen saturation level without the need of drawing blood samples in 1976 with the HP 47201A eight-wavelength ear oximeter.<sup>1</sup> An earprobe was coupled through a fiber-optic cable to the oximeter mainframe, which contained the light source (a tungsten-iodine lamp and interference filters for wavelength selection) and receivers. This instrument served as a “gold standard” for oximetry for a long time and was even used to verify the accuracy of the first pulse oximeters in clinical studies.

The real breakthrough came in the 1980s with a new generation of instruments and sensors that were smaller in size, easier to use, and lower in cost. These new instruments used a slightly different principle from the older, purely empirical multiwavelength technology. Instead of using constant absorbance values at eight different spectral lines measured through the earlobe, the new pulse oximeters made use of the pulsatile component of arterial blood generated by the heartbeat at only two spectral lines. The necessary light was easily generated by two light-emitting diodes (LEDs) with controlled wavelengths. Small LEDs and photodiodes made it possible to mount the optical components directly on the sensor applied to the patient, avoiding the necessity of clumsy fiber-optic bundles.

## Instruments and Sensors

The first pulse oximeters were standalone products. HP offered its first pulse oximetry devices as additional measurements for an existing monitoring product, the HP 78352/54 family, in 1988. A year later the Böblingen Medical Division introduced a new modular patient monitor, the Component Monitoring System,<sup>2</sup> for which a pulse oximeter module was also available, the HP M1020A (Fig. 1). The application was limited to adults and the only sensor available was the HP M1190A, an advanced design at that time. This sensor is the ancestor of the new sensor family presented in this paper.

Two years later, the HP 78834 neonatal monitor extended  $\text{SpO}_2$  measurement to newborn applications. Third-party sensors were used.

Today, all typical monitoring application areas have discovered pulse oximetry: intensive care, operating rooms, emergency, patient transport, general wards, birth and delivery, and neonatal care. HP monitors serving these areas include the HP M1025A anesthetic gas monitor (1990), the HP Component Transport Monitor (1992),  $\text{SpO}_2$  options for the HP M1722A and M1723A CodeMaster XL defibrillators (1994, Fig. 2), and recently, the HP M1205A OmniCare monitor and the HP 1350B maternal  $\text{SpO}_2$  option for the HP XM Series fetal monitors (Fig. 3).

## New $\text{SpO}_2$ Sensor Family

A new family of reusable HP pulse oximetry sensors is now available (Fig. 4). Lower in cost than previous reusable sensors and easier to use than adhesive disposable sensors, the new HP  $\text{SpO}_2$  sensor family is hardware compatible with HP's installed base of pulse oximetry front ends. An upgrade to the software is necessary to update the calibration constants in the instrument algorithms to match the optical characteristics of the new sensors, such as spectra and intensity. The new

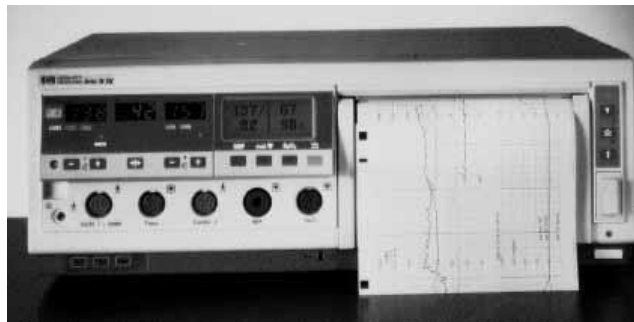




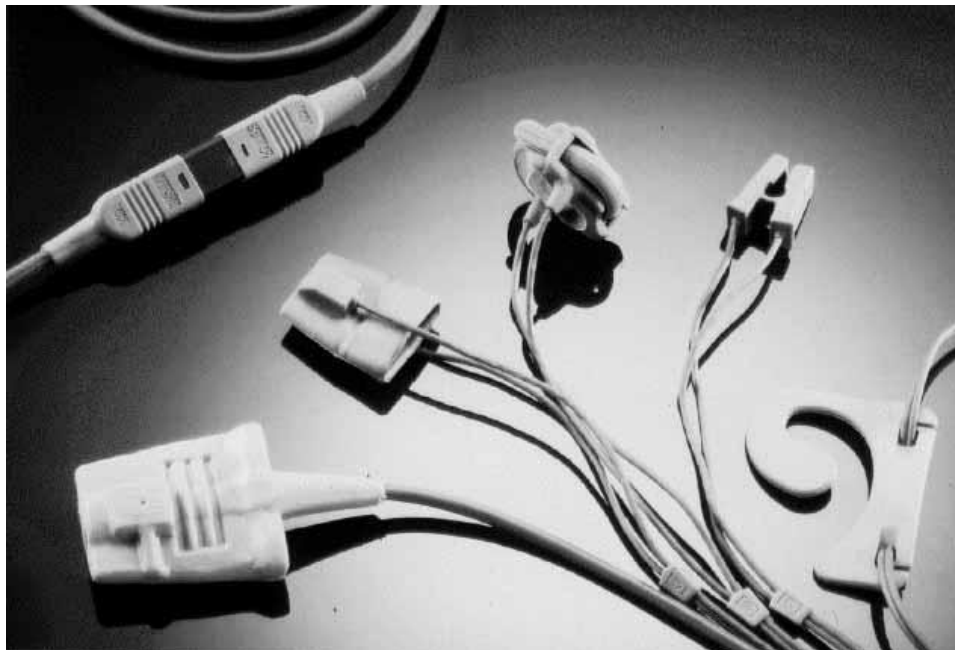
**Fig. 1.** The HP M1020A SpO<sub>2</sub> front-end module for the HP Component Monitoring System.



**Fig. 2.** An HP CodeMaster defibrillator with SpO<sub>2</sub> channel.



**Fig. 3.** The SpO<sub>2</sub> channel in an HP XM Series fetal monitor monitors the mother during delivery.

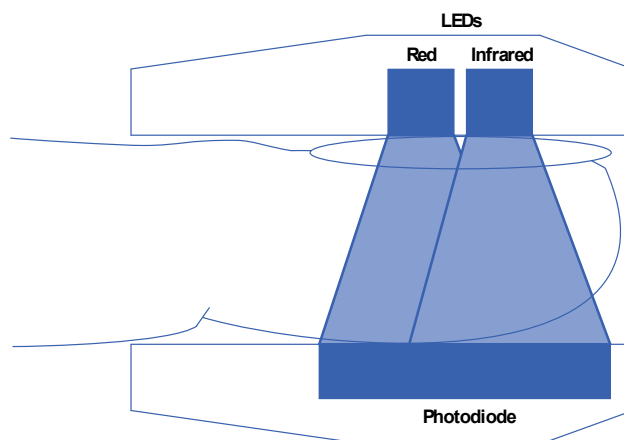


**Fig. 4.** The new family of reusable HP pulse oximetry (SpO<sub>2</sub>) sensors: (left to right) adult finger glove, pediatric finger glove, neonatal foot strap, ear clip.

sensor family covers all application areas and consists of the HP M1191A (adult, new wavelength), M1192A (pediatric), M1193A (neonatal), and M1194A (clip).

### SpO<sub>2</sub> Basic Measurement Principles

The breakthrough from oximetry to pulse oximetry came with the new LED technology in 1982 to 1985. LED light sources are very small and easy to drive, and have the great advantage that they can be mounted within the sensor together with a photodiode receiver (Fig. 5). For correct measurements at least two LEDs with different wavelengths are necessary. A suitable combination consists of a red LED (650 nm) and an infrared LED (940 nm). The red LED's wavelength has to be in a narrow range, which is not normally possible with standard commercially available LEDs. One way to overcome this is to provide in each sensor a calibration resistor matched to the actual LED wavelength. Another way is to select only LEDs with a fixed wavelength. This method becomes practical if the LED wafer production yields a narrow wavelength distribution. HP decided on this second method because the red LEDs could be obtained from the HP Optoelectronics Division, which had long experience in wafer production and was able to maintain a sufficiently narrow wavelength distribution.



**Fig. 5.** The basic components of an SpO<sub>2</sub> pulse oximeter sensor are two LEDs with different wavelengths as light sources and a photodiode as receiver.

The front-end hardware applies a time multiplexed approach in which the two LEDs are switched on and off alternately. The time phases usually consist of a minimum of three: active red, active infrared, and a dark phase in which the ambient light is measured. There can be more than three phases to allow more LEDs to be powered in one multiplexing time frame or to allow additional dark phases. The phases are similar in duration. The modulation frequency (the complete frame repetition rate) typically ranges from 200 Hz to 2 kHz. The frequency spectrum of such a time multiplexed signal at the receiving photodiode consists of small bands (approximately  $\pm 10$  Hz) around the modulation frequency and its harmonics. Depending on the width of the individual LED pulses, the harmonic frequency content is of significant amplitude for several tens of harmonic orders.

For an idealized light absorbing model as shown in Fig. 6, the Lambert-Beer law applies. The intensity  $I$  of the light transmitted is related to the incident light  $I_0$  by:

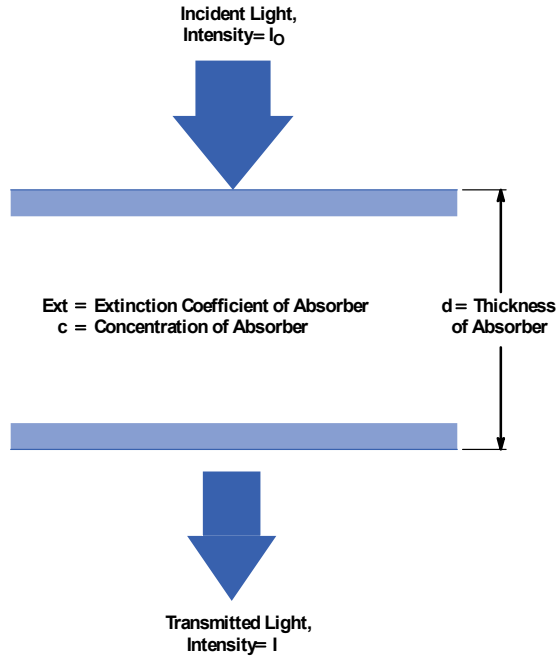
$$I = I_0 \exp(-\text{Ext} \cdot c \cdot d), \quad (1)$$

where  $\text{Ext}$  is the extinction coefficient and  $c$  is the concentration of a single light absorber with thickness  $d$ .  $\text{Ext}$  varies as a function of the absorbing substance and the wavelength of the light. Further assumptions for the validity of equation 1 are that the light source is monochromatic and has parallel propagation and that the absorber is optically homogeneous (no scattering effects).

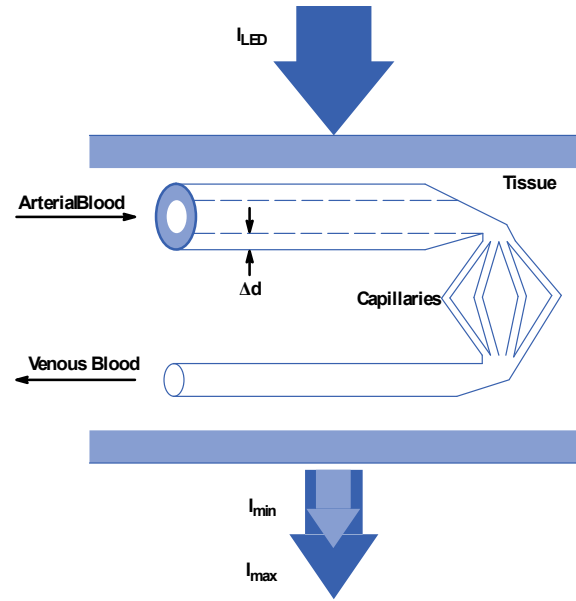
Under these assumptions the model of Fig. 6 can be used to derive the basic pulse oximetric quantities. Fig. 7 shows a simplified model for the blood vessel system in tissue. With each heartbeat, the volume of the arteries increases before the blood is forced into the capillaries and from there into the veins. This change of arterial volume is the basis for pulse oximetry because it makes it possible to separate the arterial blood from all other absorbing substances.

Assume that there are  $N$  layers of absorbers and that the  $i$ th absorber layer has concentration  $c_i$ , thickness  $d_i$ , and extinction coefficient  $\text{Ext}(i, \lambda)$ . From equation 1 it follows, at diastole, when there is a maximum of light intensity:

$$I_{\max}(\lambda) = I_{\text{LED}}(\lambda) \exp\left(-\sum_{i=1}^N \text{Ext}(i, \lambda) c_i d_i\right). \quad (2)$$



**Fig. 6.** Idealized model for the validity of the Lambert-Beer law: a monochromatic light source, parallel light propagation (no point source), and no scattering.



**Fig. 7.** Simplified model for the blood vessel system. With each heartbeat, the arterial radius expands by an amount  $\Delta d$ , which yields a light intensity change from  $I_{\max}$  to  $I_{\min}$ .

At systole, the maximum of the heartbeat, and under the assumption that only hemoglobin and oxyhemoglobin are active absorbers in the arterial blood, two additional absorbing parts are added in the exponent of equation 2, which yields the minimum of light intensity:

$$I_{\min}(\lambda) = I_{\max}(\lambda) \exp(-\Delta d (\text{Ext}(\text{Hb}, \lambda)[\text{Hb}] + \text{Ext}(\text{HbO}_2, \lambda)[\text{HbO}_2])), \quad (3)$$

where  $[\text{Hb}]$  is the concentration of hemoglobin and  $[\text{HbO}_2]$  is the concentration of oxyhemoglobin. Dividing equation 2 by equation 3 and taking the logarithm yields the absorption of the arterial blood:

$$\ln\left(\frac{I_{\max}(\lambda)}{I_{\min}(\lambda)}\right) = \Delta d (\text{Ext}(\text{Hb}, \lambda)[\text{Hb}] + \text{Ext}(\text{HbO}_2, \lambda)[\text{HbO}_2]), \quad (4)$$

where  $\Delta d$  is the change in the arterial radius (see Fig. 7). The definition for the oxygen saturation in pulse oximetry is:

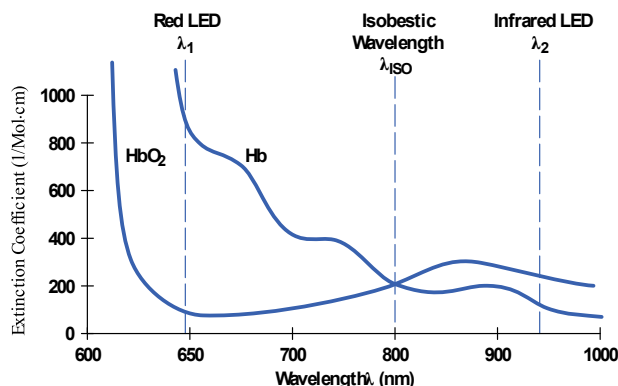
$$\text{SpO}_2 = \frac{[\text{HbO}_2]}{[\text{Hb}] + [\text{HbO}_2]}. \quad (5)$$

With two light sources (LEDs) of different wavelengths  $\lambda_1$  and  $\lambda_2$  the arterial expansion  $\Delta d$  can be eliminated by the following relation, which is called the ratio,  $\mathbb{R}$ :

$$\begin{aligned} \mathbb{R} &= \frac{\ln\left(\frac{I_{\max}(\lambda_1)}{I_{\min}(\lambda_1)}\right)}{\ln\left(\frac{I_{\max}(\lambda_2)}{I_{\min}(\lambda_2)}\right)} \\ &= \frac{\text{Ext}(\text{Hb}, \lambda_1)(1 - \text{SpO}_2) + \text{Ext}(\text{HbO}_2, \lambda_1)\text{SpO}_2}{\text{Ext}(\text{Hb}, \lambda_2)(1 - \text{SpO}_2) + \text{Ext}(\text{HbO}_2, \lambda_2)\text{SpO}_2}. \end{aligned} \quad (6)$$

Thus, the oxygen saturation  $\text{SpO}_2$  is:

$$\text{SpO}_2 = \frac{\mathbb{R} \text{Ext}(\text{Hb}, \lambda_2) - \text{Ext}(\text{Hb}, \lambda_1)}{\mathbb{R}(\text{Ext}(\text{Hb}, \lambda_2) - \text{Ext}(\text{HbO}_2, \lambda_2)) + \text{Ext}(\text{HbO}_2, \lambda_1) - \text{Ext}(\text{Hb}, \lambda_1)}.$$

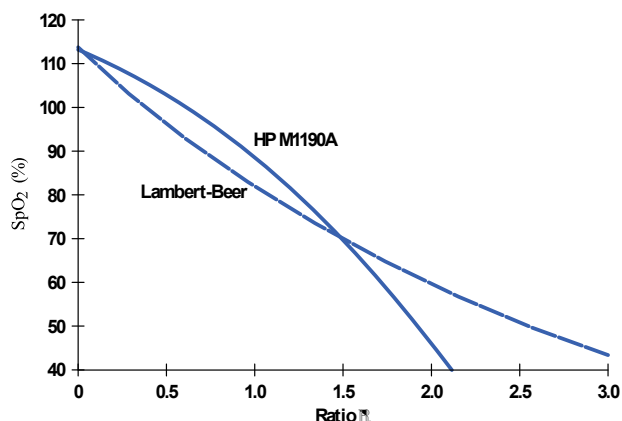


**Fig. 8.** Extinction coefficients for hemoglobin Hb and oxyhemoglobin HbO<sub>2</sub> as a function of wavelength. A red LED with  $\lambda = 650$  nm gives good resolution between HbO<sub>2</sub> (100%SpO<sub>2</sub>) and Hb (0%SpO<sub>2</sub>).

For example, with LED wavelengths  $\lambda_1 = 650$  nm and  $\lambda_2 = 940$  nm, the extinction coefficients are (see Fig. 8):

$$\begin{aligned} \text{Ext}(\text{Hb}, 650) &= 820 \text{ (Mol} \cdot \text{cm)}^{-1} \\ \text{Ext}(\text{HbO}_2, 650) &= 100 \text{ (Mol} \cdot \text{cm)}^{-1} \\ \text{Ext}(\text{Hb}, 940) &= 100 \text{ (Mol} \cdot \text{cm)}^{-1} \\ \text{Ext}(\text{HbO}_2, 940) &= 260 \text{ (Mol} \cdot \text{cm)}^{-1}. \end{aligned}$$

In Fig. 9 the SpO<sub>2</sub> is plotted as a function of the ratio  $R$ . The Lambert-Beer relation is compared with a calibrated curve derived from real arterial blood samples from volunteers (see subarticle “**Volunteer Study for Sensor Calibration**”). The deviations exist because conditions in the real case (complicated tissue structure, scattering effects, point light source, etc.) are different from the Lambert-Beer assumptions.



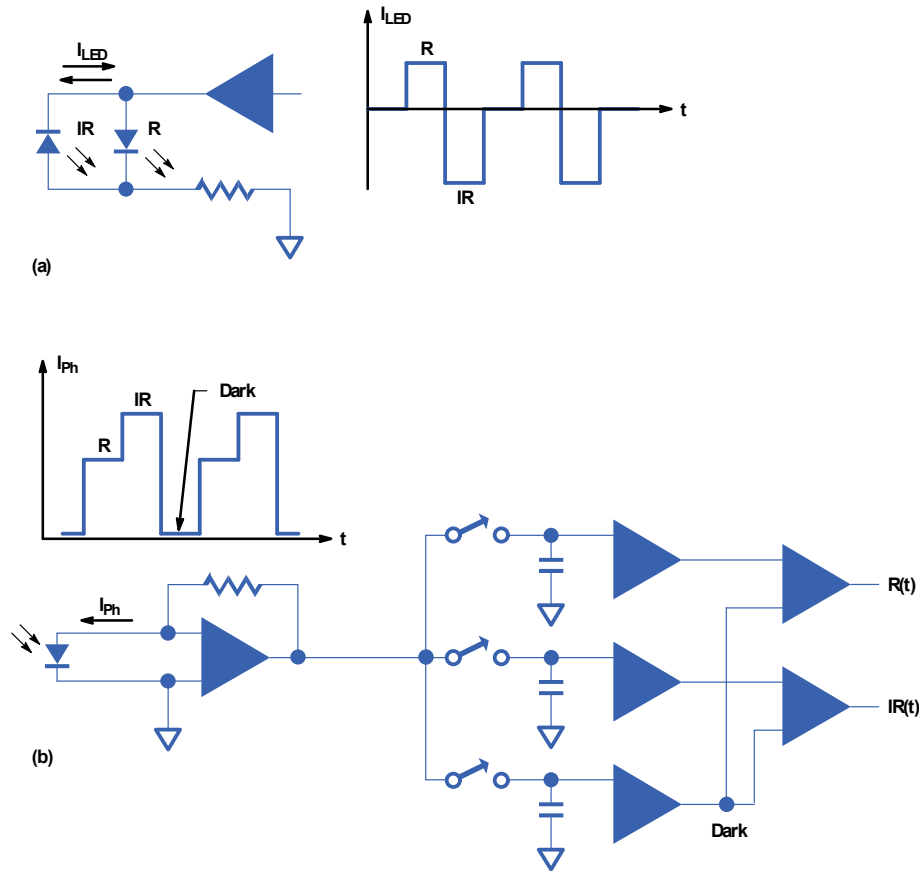
**Fig. 9.** Theoretical (Lambert-Beer) and real calibration (arterial blood samples) curve for the HP M1190A adult sensor. The difference is mainly caused by scattering effects and nonideal light sources.

Fig. 10 shows the sensor LED driver circuit and receiver circuit. The LEDs are driven in sequence at a repetition rate of 375 Hz in antiparallel fashion. At the photodiode the intensities arrive in the sequence red (R), infrared (IR) and dark. In the receiver circuit this signal is split into three paths: a red path, an infrared path, and a dark path. The dark intensity is subtracted from the red and infrared.

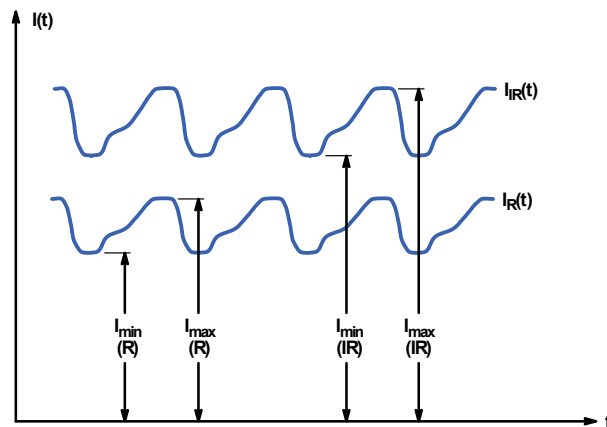
Fig. 11 shows the separated red and infrared patient signals with their  $I_{\min}$  and  $I_{\max}$  values caused by arterial pulsation, from which the ratio  $R$  can be calculated (equation 6).

### Ambient Light and Electrical Noise

In a clinical environment, the sensor picks up ambient light and electromagnetic noise from various sources. The major source for ambient light is room illumination, typically fluorescent ceiling lamps, which have broad spectral bands with peaks at harmonics of the power-line frequency, 50 Hz or 60 Hz. Very often, electrical noise also comes from the power line and shows up as harmonics of the line frequency. Other well-known sources of large interfering electrical signals are the electrosurgery devices used in operating rooms, which can be very broadband.



**Fig. 10.** (a) Sensor LED driver circuit and (b) receiver circuit.



**Fig. 11.** Separated red and infrared patient signals with their  $I_{\min}$  and  $I_{\max}$  values caused by arterial pulsation.

Typical current levels at the sensor photodiode are around 1  $\mu\text{A}$  dc with the blood current pulse modulated on the dc levels at a modulation depth of typically one percent. It is likely that the LED spectra including the desired signal and the optical or electrical noise spectra will overlap. Any noise lines in one of the LED modulation bands will be demodulated and folded down to the baseband, where they will contribute to poor signal-to-noise ratio (S/N). A very dangerous situation for the patient can occur in the monitoring of neonates, who are often treated with very bright UV lamps for bilirubin phototherapy. Neonates give poor  $\text{SpO}_2$  signals because of poor vascular perfusion, so the bright UV ambient light can cause situations in which  $\text{S/N} < 1$ . A pulse oximeter is very likely to be misleading in these situations. It can derive values for pulse rate and oxygen saturation that are wrong because the input signals are dominated by noise.

Because interference can lead clinicians to apply incorrect care and therapy and cause harm or even death to patients, it must be avoided at all costs. A major goal for the sensor design was optimum optical and electrical shielding. Fig. 12 shows the pediatric sensor. Its closed housing is designed to shield the sensor from interfering ambient light.



**Fig. 12.** The HP M1192A pediatric sensor has a closed housing to shield it from interfering ambient light.

### **Movement Artifacts**

Because the pulse oximetry method relies on the pulsatile part of the absorption, probably the most frequent cause of trouble is movement of the patient. Any movement usually causes movement of the sensor or the nonarterial tissue under the sensor and thereby leads to noise on the signals. A design goal for the new sensors was to be small and lightweight and to attach firmly to the patient. The cable was made as thin and flexible as possible consistent with the need for robustness, so that it adds little weight and stiffness, thereby helping to decouple the sensor from cable movements.

### **Cable Robustness**

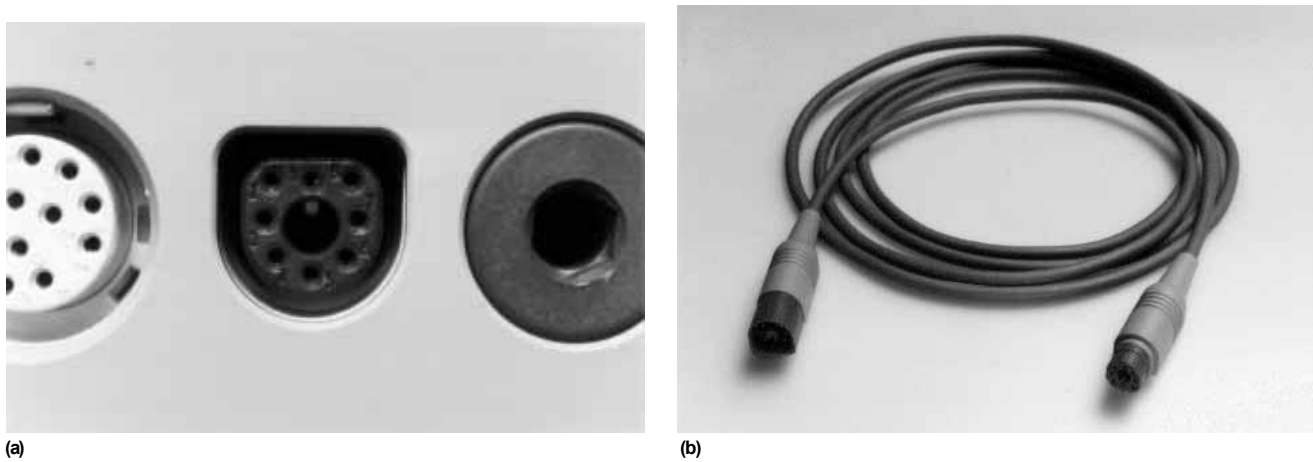
The clinical environment can be very harsh. Sensors fall off patients. People step on them and carts roll over them. Cables get squeezed between drawers and racks. The cables of medical sensors, in particular, have to be extremely robust. They are moved, bent, kinked, and treated with aggressive disinfectants.

A carefully selected lead composition and the use of nonbreakable material were goals for the cable construction. A new connector and interconnection concept are used. The interconnection is split into two parts: a short, thin, and more fragile cable is used with the sensors for low weight and minimum mechanical stiffness, while a longer, heavier, more robust cable was designed as an interface cable to the instrument.

The connector joining the cables (Fig. 13) is optimized for small size, low weight, and robustness. Special care was taken to provide very high insulation between the pins and to make the interconnect junction watertight to avoid leakage currents in humid environments like neonatal incubators. In older designs, saturated water vapor and salty residues from infusions or blood on connectors was a common source of problems, leading to erroneous measurement results.

### **Setting Design Goals**

HP has offered a reusable SpO<sub>2</sub> sensor since 1988, but in one size only: the adult HP M1190A sensor. This sensor is very well-accepted. The objective for the new sensor project was to extend this sensor technology to a family of sensors covering all of the different application areas, so the customer is not forced to use a third-party sensor for application reasons.



**Fig. 13.** Plug and socket connector system.

Based on experience with the HP M1190A sensor and on customer feedback we defined the following objectives:

- “Must” Objectives
  - Reusable sensors only
  - Cost competitive with disposable sensors
  - Clear, nonconfusing application
  - No burns on skin
  - State-of-the-art necrosis factor behavior (minimal local cell damage)
  - No penumbra effect
  - Influence of ESI (electrosurgery interference) as low as in HP M1190A
  - Backward compatibility with HP monitors (hardware)
- “Want” Objectives
  - Reliability equal to HP M1190A
  - Easy to use
  - Comfortable application over long period of time (several days)
  - Reliable fixing mechanism
  - Cleaning and sterilization by immersion in solutions
  - Mechanically robust design like HP M1190A
  - Cable size, length, flexibility, and quality similar to HP M1190A; alternatively, trunk cable and sensor cables
  - No influence of ambient light (operating room, bilirubin therapy, fluorescent lights)
  - Minimum motion artifacts
  - Backward compatibility with HP monitors (software)
  - Compatibility with competitive monitors.

Reusability was required because HP feels environmentally responsible for HP products. Most of the sensors on the market are disposable, which means that they are applied only once, after which they must be disposed of as medical waste. Reusable sensors are a small contribution to protecting the environment.

We used the Quality Function Deployment<sup>3,4</sup> (QFD) tool for developing these sensors. The starting point for QFD is the customer—what does the customer want? The customer requirements are weighted according to their relative importance, the corresponding engineering characteristics are listed, and step by step a matrix is built that provides the means for interfunctional planning and communication.

The three most important customer attributes we found are:

- **Functionality.** Minimize physiological effects like skin irritation and low perfusion. This means selecting the appropriate material and applying the appropriate clamping force.
- **Performance.** Ensure good signal quality. The most important issue was to select optical components to provide good light transmission.
- **Regulations.** The sensors had to meet U.S. FDA requirements and international safety and EMC standards.

We have had several clinical trials to verify that we understood the customer requirements correctly. At the release of the product for manufacturing we checked our solutions again to make certain that they are in accordance with the required customer attributes and engineering characteristics. We have been shipping the sensors for over half a year without any customer objections. This makes us fairly confident that the sensors meet customer expectations.



## Design Concept

The next step after defining the project goals was to evolve the basic design concept. To reduce waste (even reusable parts have to be replaced eventually) we decided that each transducer would consist of two parts: an adapter cable to be used for all sensors and a sensor cable consisting of connector, transmitter, receiver, and a special sensor housing for the specific application site (finger of a child or small adult, foot or hand of a neonate, ear of an adult). We made this split since the lifetime of the adapter cable is longer (we estimated three times longer) than that of the sensor cable, which is much lighter in weight to reduce motion artifacts. A further advantage of the two-part design is the flexibility for future products to use the sensor without an adapter cable. The design required the development of a new 8-pin connector family.

To minimize the risk, because of the very good customer feedback for the existing adult sensor, we decided to change only the optical elements of the transducer.

The detailed design concept is shown in Fig. 14. The adapter cable is a shielded twisted-pair cable with four single conductors, a 12-contact male plug on the instrument side, and an 8-contact female connector on the sensor side. The sensor cable is a shielded twisted pair cable with two conductor pairs, an 8-contact male plug on the instrument side, a transducer consisting of transmitter and receiver molded in epoxy, and a special sensor housing.

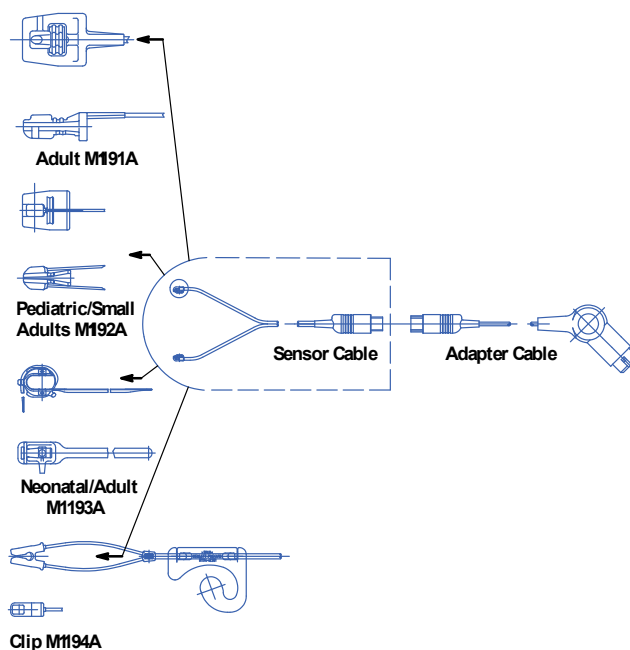


Fig. 14. Design concept for the new sensor family.

## Housing

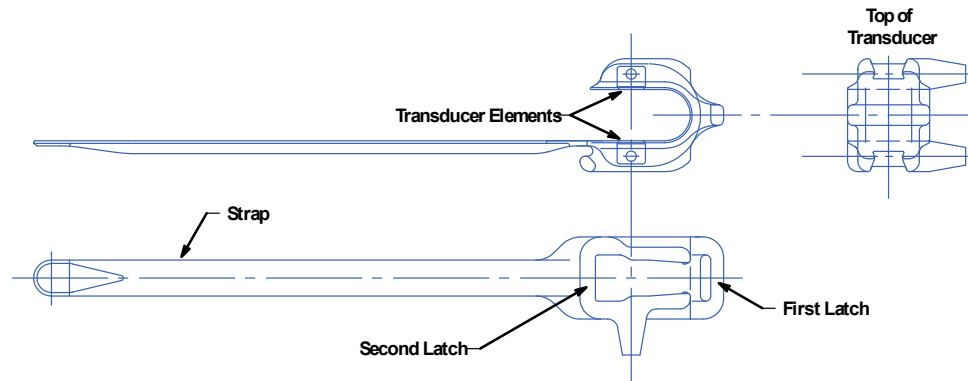
With the project goals in mind, the first proposals for the sensor housing were designed and prototype tooling was ordered to get parts ready for the first application tests. It was especially necessary to start with application tests as soon as possible for the neonate sensor, because this sensor would cover the biggest area and would be the most sensitive. The design of the pediatric sensor was more straightforward. It had to be similar to the existing adult sensor. For the other two sensors we approved a couple of proposals and ordered the prototype tooling for those.

With these samples we went into hospitals and spoke to nurses and medical technicians. When their response was positive, we began to improve the design step by step, making all changes in the prototype tooling as far as possible. If it was not possible to realize a necessary change, new prototype tooling was ordered. Only after this iterative process was complete did we order the final tooling.

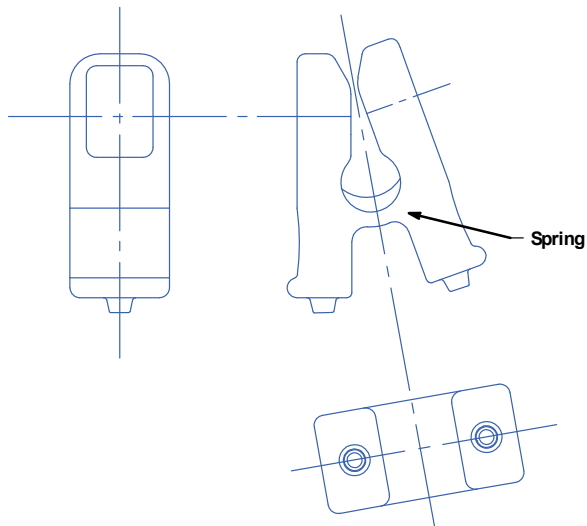
The idea for the neonatal sensor, Fig. 15, was to place the transducer elements facing one another to make it easier to apply the sensor on foot or hand, and to have a long strap with a special fastener that allows application of the sensor on different foot or hand sizes. The transducer is positioned on the foot or the hand and the strap is threaded through the first latch and pulled slightly while holding the top of the transducer. The second latch is only used if the strap is too long.

The idea for the clip sensor was to integrate the spring for the necessary clamping force into the molded part (Fig. 16). The transducer is clipped onto the fleshy part of the earlobe. To minimize motion artifacts generated by patient movements a plastic fixing mechanism that hooks over the ear is provided.

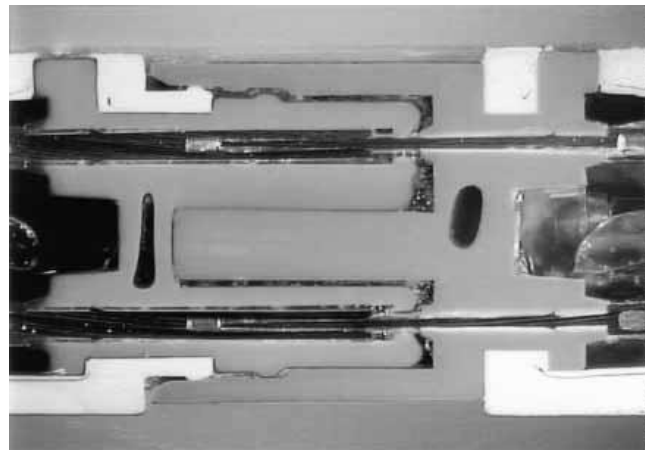




**Fig. 15.** Neonatal sensor.



**Fig. 16.** Clip sensor.



**Fig. 17.** Cutaway view of two pins of the 8-pin connector between the adapter cable and the sensor cable. The connector is watertight when joined.

## Cable and Connector

Three different types of cables are used for the sensor family. For the adapter cable we use a very robust cable with an outer jacket made of polyurethane. The same adapter cable is used with all of the sensor types.

Two different sensor cables are used, one for the adult transducer and another for the rest of the family. They differ only in the outer jacket. For the adult sensor the outer jacket is made of silicone because of the manufacturing process. The sensor housing, which is made of silicone, is molded together with the cable and other elements in a molding machine. Because silicone can't be combined very well with different materials, the outer jacket must also be silicone.

For the rest of the sensor family we use a split, lightweight cable with an outer jacket made of polyurethane.

The construction of all three cables is similar. All are twisted-pair and have a Kevlar braid anchored in both the sensor and the connector to improve the strain relief.

The 8-pin connector between the sensor cable and the adapter cable also has a soft outer jacket made of polyurethane. The Kevlar braid is anchored inside the connector. Watertightness is achieved when the two halves of the connector are joined (see Fig. 17).

## Optical Components

The optical elements are mounted on ceramic substrates shaped by cutting with a high-energy laser. The transmitter (Fig. 18) consists of two LED die (red and infrared) mounted on gold metallization. A photodiode on the receiver ceramic (Fig. 19) receives the sensor signal. A dome of epoxy material protects the elements and bond wires from mechanical stress. The wires of the transducer and the Kevlar braid are soldered and anchored on the backside of the ceramic.

To a first approximation, LEDs have a Gaussian intensity spectrum in which the peak wavelength is equal to the centroid wavelength. Because the red area ( $< 650$  nm) of the extinction coefficients is very sensitive to wavelength variation (see Fig. 8) and the intensity distribution is not actually Gaussian and symmetrical, we use the centroid wavelength, which differs slightly from the peak wavelength, as an adequate characterization parameter for the LED (Fig. 20). Normally the

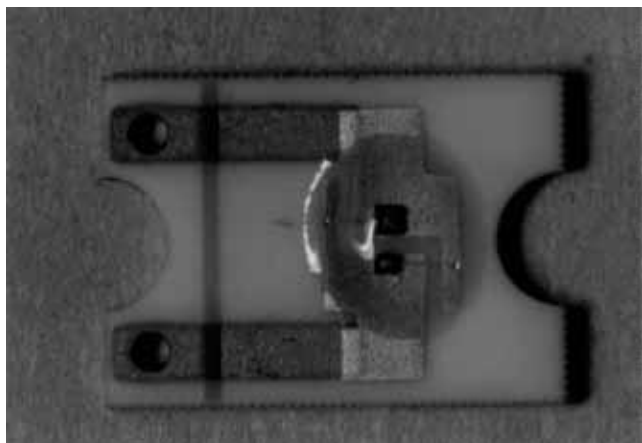


Fig. 18. LED transmitter.

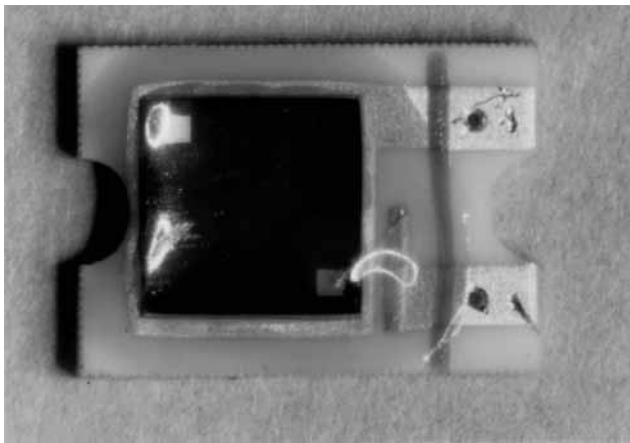


Fig. 19. Photodiode receiver.

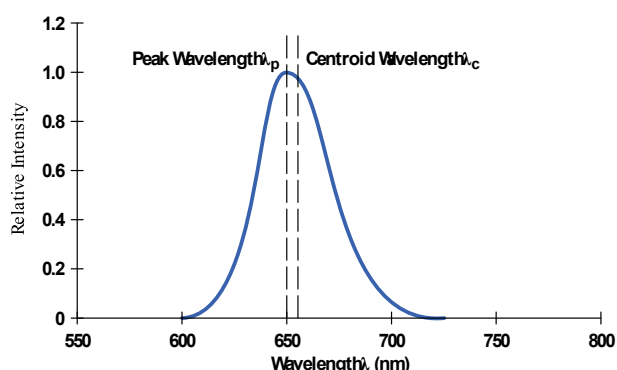


Fig. 20. A typical LED intensity distribution. For SpO<sub>2</sub> measurements the centroid wavelength gives a better characterization than the peak wavelength.

wavelength variation on a preselected wafer for red LEDs is in the range of  $\pm 5$  nm. For the HP M1190A sensor in 1990, the HP Optoelectronics Division installed a selection process for a narrow,  $\pm 1$ -nm centroid wavelength variation.

For the new sensor family we chose for each sensor an LED pair with centroid wavelengths of 660 nm (red) and 890 nm (infrared). For the red LED a new high-efficiency AlGaAs technology was chosen. The maximum intensity for these LEDs is about a factor of four higher than for the older ones. This has the big advantage that the transmission values for both the red LEDs and the infrared LEDs are about the same. The average drive current for the LEDs, and therefore the heat dissipation, can be dramatically lowered.

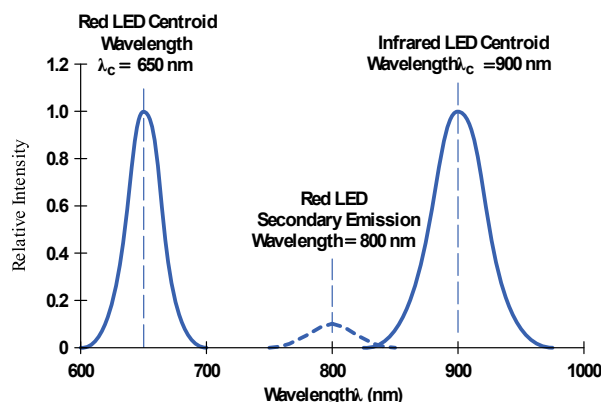
The transmission  $Tr$  is defined as the ratio of photocurrent to LED current:

$$Tr = \frac{I_{ph}}{I_{LED}}, \quad (8)$$

where  $I_{ph}$  is in nanoamperes and  $I_{LED}$  is in milliamperes.  $Tr$  depends strongly on the absorption and extinction coefficients of the patient's tissue. Mean values are about 70 nA/mA over a large patient population. For thin absorbers like the earlobe, values of  $Tr$  as high as 300 nA/mA are possible. With new SpO<sub>2</sub> front-end hardware this would not have been a problem, but to be compatible with older pulse oximetry instruments we use a smaller active area of the photodiode for the HP 1194A ear sensor to get the same  $Tr$  values as the other sensors.

The LED supplier (not HP for the new sensors) guarantees a narrow centroid wavelength variation of less than  $\pm 2$  nm. For LED qualification measurements, an optical spectrum analyzer with a wavelength resolution of 0.2 nm is used. All LED parameters are measured with a constant drive current of 20 mA. Because there is a wavelength shift over temperature of about 0.12 nm/K, the ambient temperature has to be held constant. Depending on the LED packaging, there is also a certain warmup time, which has to be held constant for LED qualification. In clinical practice, there can always be a temperature shift during SpO<sub>2</sub> measurements, but because of the definition of the ratio  $R$ , with red intensity in the numerator and infrared intensity in the denominator (see equation 6), this effect is compensated within the specified operating temperature range of  $15^\circ\text{C} < T < 45^\circ\text{C}$ .

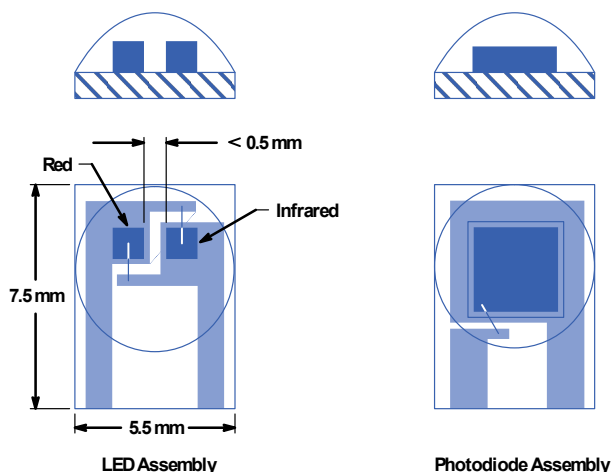
Another important factor is that some red LEDs have a low secondary emission ( $< 4\%$  of maximum intensity) at a wavelength of typically 800 to 850 nm (Fig. 21). For higher secondary intensities, interference with the infrared LED causes a ratio error and therefore an  $\text{SpO}_2$  error, which must be eliminated. For the new high-efficiency LEDs the secondary emission is typically less than 0.1%



**Fig. 21.** Typical red and infrared LED spectra for  $\text{SpO}_2$  sensors. The spectral half-bandwidth for the red LED is about 20 nm and for the infrared LED about 40 nm. A secondary emission peak for the red LED is undesired and has to be lower than 4% of the maximum intensity.

The receiver element is a standard silicon photodiode with peak sensitivity at 850 nm. The active area is approximately 2 mm square for the HP M1191/92/93A sensors and 1 mm square for the HP M1194A ear sensor. The die are mounted on a ceramic substrate with metalized layers for shielding.

The package for the LEDs in the HP M1190A sensor was a standard subminiature package. The emitter consisted of a red-infrared-red triplet in a longitudinal arrangement to make the apparent emission points for the red and infrared sources virtually identical. This is important for the ratio calculation, because both light paths have to be about the same length. One disadvantage is a possible malfunction when the patient's finger does not cover the entire light source. Then a part of the red light can cause an optical shunt that yields dc red levels that are too high (penumbra effect), causing false high readings. In the new sensor design, the two LEDs are very close together ( $< 0.5$  mm) on a common leadframe (see Fig. 22). This should eliminate the penumbra effect.



**Fig. 22.** Transmitter and receiver assemblies for the new sensor family are on ceramic substrates. To avoid asymmetric optical shunting (penumbra effect) the two LED die are mounted as close as possible to each other. An epoxy coating is added before final packaging to protect the optical parts.

The die are mounted on a ceramic substrate and covered with a transparent epoxy material. A design goal was to get a water and disinfectant resistant seal between the cable and the package. Immersion and disinfection tests show that this goal was achieved.

## Materials

For the pediatric and neonatal sensors we chose silicone with a hardness of  $35 \pm 5$  Shore A. The material is very robust and has good tensile strength compared to other silicones. Silicone is very often used in clinical areas and is very well-accepted. It is very resistant to chemicals and causes no skin irritations when used correctly.

For the clip sensor we chose a polyurethane with a hardness of  $75 \pm 5$  Shore A, which gives the required clamping force (Fig. 23).

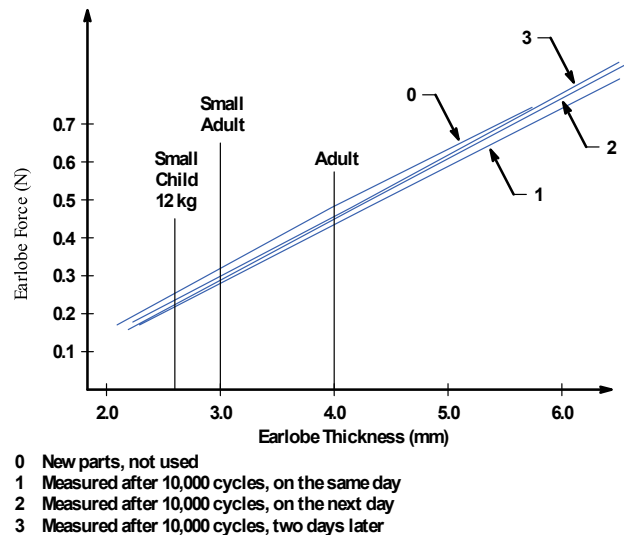


Fig. 23. Spring forces in the clip sensor.

## Manufacturing Process

The manufacturing process for the new HP M1191A sensor is injection molding, the same as for the older HP M1190A. These sensors use only silicone rubber. For the HP M1192/ 93/94A sensors a different manufacturing process was necessary because these sensors use two different materials—silicon rubber and polyurethane, which do not combine well in the injection molding process. We also wanted to reduce the manufacturing costs and to gain more flexibility in choosing suppliers.

We decided to cast the premounted optical elements together with the cable in a special epoxy that combines very well with the cable including the Kevlar braid. We thus ensured watertightness, which means the sensors can be disinfected by immersion in solutions.

## Reliability

To reach the reliability goals a few iterative changes were necessary and different tests installed. Many tests and customer visits were conducted to ensure that the sensors will not break. We tested several housing materials until we found the right one for the rough clinical environment. The tensile strength and robustness have been improved dramatically compared to the first samples. The method of anchoring the Kevlar braid in the ceramic substrate and connector was also improved several times. Every prototype was tested in the same way, by a combination of mechanical stress and cleaning by immersion in different solutions.

## Technical Qualification

The most important factor for qualifying the new SpO<sub>2</sub> sensors has been how to determine test methods that are able to expose any weak points of the design. The qualification stress should be higher than the normal clinical application stress to provoke failures. The fulfillment of customer expectations concerning reliability was the overall guideline for prioritizing the test emphasis. Because of its customer orientation, the QFD methodology was an excellent tool for determining the main focus for testing. To make QFD more practical, we divided the sensor into three subelements, which made the specifics of the subassembly more visible. The three subelements were the interconnection, the sensor housings, and the optical assemblies.

The correlation matrix between the customer requirements and the technical specifications generated a relative importance ranking within the broad list of requested technical details. We could now determine which were the most important technical parameters. Their performance would have the greatest impact on the acceptance of the sensors in the market.

It was very important to assess the technical complexities and difficulties in the realization of technical specifications. This was the task of the engineers of a crossfunctional team chosen for their experience and ability to foresee potential problems. The correlation between expected technical difficulties and the importance of the parameters to the customer was an

essential input for further activities. We could now focus our efforts to reduce the risk potentials, which were clearly defined. High risk means high importance correlated with high technical difficulty ratings. These high-priority items were communicated to the project managers to give them an impression of the degree of technical maturity in this early project phase.

A critical assessment of design risk potential could now be made. This triggered a review of the importance of each customer requirement and gave the designers valuable inputs for design concepts. The results were also useful when considering strategies for accelerated stress testing.

The next step in the QFD process was to transfer the information on high-priority technical requirements into another matrix showing the relationship between parts characteristics and technical requirements. The key deliverables of this exercise were:

- Identification of key parts and their characteristics
- Preselection of parts characteristics to find critical parts for performing a design failure mode and effect analysis (FMEA)
- Information to aid in selecting between design alternatives to find the most competitive design concepts
- Inputs for stress testing using parts characteristic importance information.

The FMEA generates risk priority numbers (RPN). These numbers describe how often a failure will occur, how easily it will be detected, and how severe the failure will be. Taking the interconnection as an example, the risk assessment was divided into three categories:

- High Risk: RPN > 200 and high parts importance
- Medium Risk: RPN > 100 and high parts importance
- Low Risk: RPN > 100 and low parts importance.

In this way, key customer needs were identified and test parameters selected. We also took into account the feedback from clinical trials.

Fig. 24 gives an overview of the qualification tests that were performed to get release approval for the sensors. A special machine was designed to simulate the cable stress that occurs in hospitals. We call this test the bending/torsion test. With a calculated number of cycles, equivalent to our reliability goals, we stressed the critical cable sections to ensure that the lifetime requirements were met.

## Supplier Selection

The supplier chosen to manufacture the new SpO<sub>2</sub> sensor family had to meet a number of specific requirements. The supplier is responsible for the majority of the manufacturing process steps. This has a positive influence on production lead time, logistics, communication, and costs. To reach our quality goals with one supplier who is responsible for nearly all process steps is much easier than with a long chain of suppliers. The requirements covered technology, vertical integration, and costs.

Fourteen international suppliers were evaluated. Nine were not able to manufacture the sensors because they did not have the required technology. After considering cost aspects, only two suppliers fulfilled the selection criteria. For these two suppliers, we constructed supplier profiles derived from the QFD method.

To construct a profile, each customer need is listed along with an evaluation of how well the supplier fulfills that need in terms of technology and processes. The level of fulfillment is evaluated by an HP specialist team, which also evaluates the importance of each customer need. The profile shows the supplier's strengths and weaknesses and gives a point score. The supplier with the higher number of points is considered better qualified to manufacture these products.

To evaluate critical technology and processes, design and process failure mode and effect analyses (FMEAs) were conducted for both suppliers' products. To evaluate each manufacturer's capabilities, a quality and process audit was performed at the manufacturing site. The auditors reviewed the site and manufacturing processes for comparable products that were identified as critical for our sensor products.

## Production Wavelength Measurements

The measurement of LEDs for the SpO<sub>2</sub> sensors at the manufacturing site is a critical and sensitive manufacturing process step. To guarantee the accuracy of HP SpO<sub>2</sub> measurements the wavelength of the red LED has to be within a very small range: between 657 and 661 nm. To measure the LED wavelength a very accurate optical spectrometer is used. To obtain repeatable measurement results, an integrating sphere is used to couple the light of the red LED into the spectrometer (see Fig. 25).

An integrating sphere is a ball with a highly reflective surface. The light is reflected many times on the surface and becomes diffuse. As a result, the spectrum and the intensity of an LED are the same at each point of the surface of the ball and can be coupled easily into the spectrometer. The main advantage of this method is that tolerances in the placement of the LED are

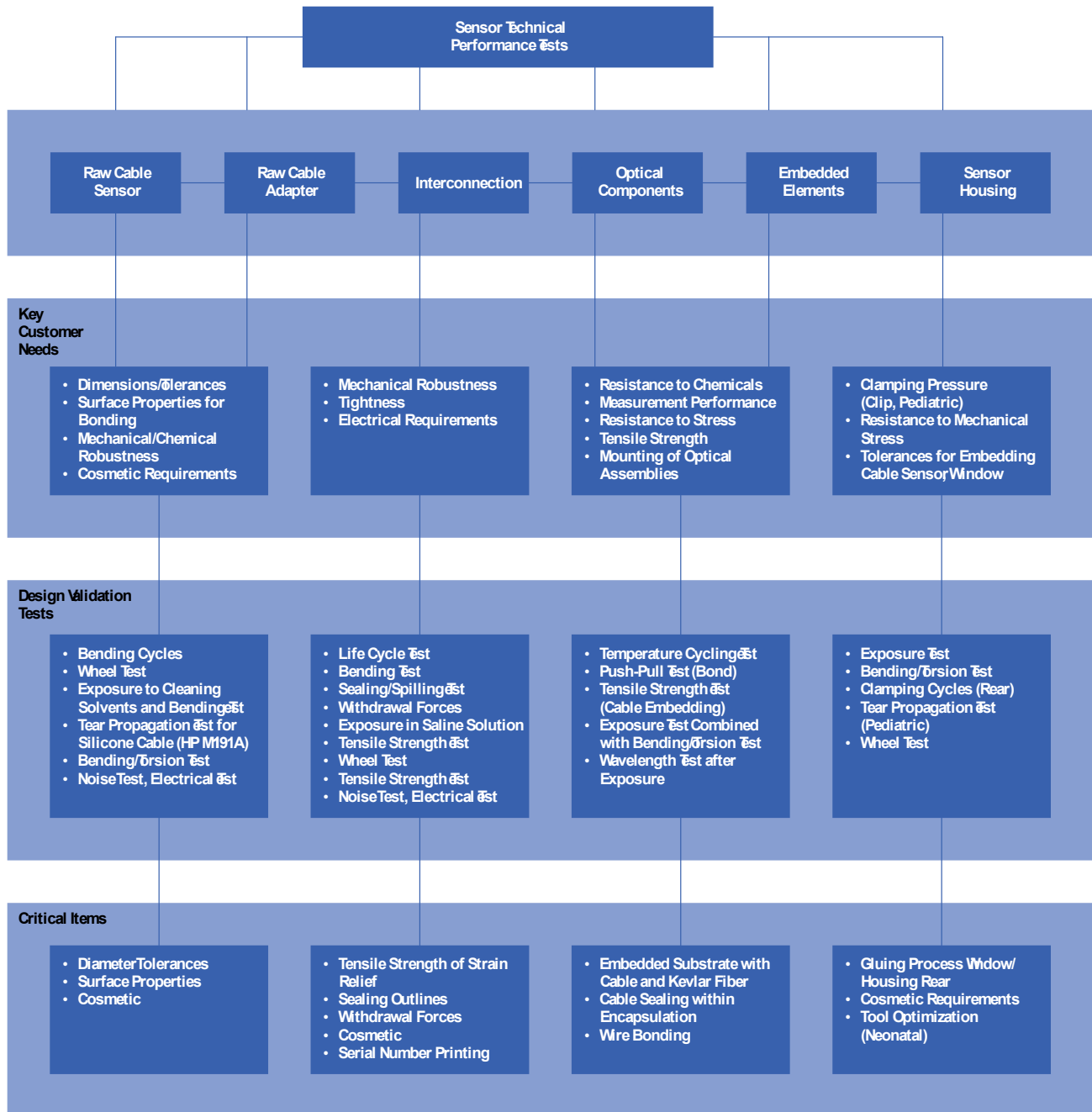


Fig. 24. Qualification tests for the new sensor family.

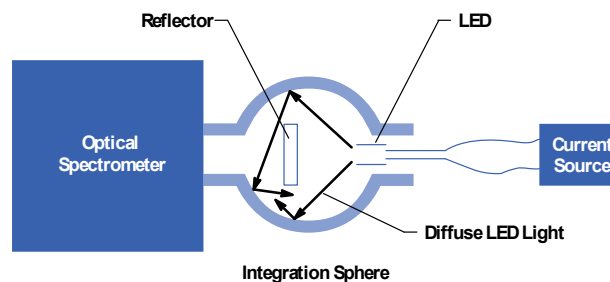
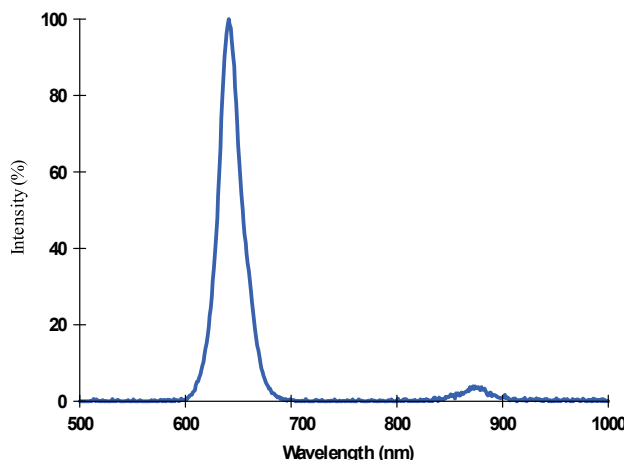


Fig. 25. Setup for LED spectral measurements.

not critical and the repeatability is very good compared to other methods. Fig. 26 shows a typical spectrum of a red LED measured with an integration sphere.



**Fig. 26.** Spectrum of a red LED measured with an integration sphere.

There are different ways to measure the wavelength of an LED. One is the peak wavelength, which is the highest point of the spectrum. The centroid wavelength, which is used in our measurements, calculates the center of the area under the spectrum. A secondary peak in the spectrum of the LED can have a large influence on the measurement results and has to be very small ( $< 1\%$ ).

The temperature of the LED die has a large influence on the emitted wavelength—the higher the temperature the higher the wavelength ( $0.12 \text{ nm/K}$ ). Therefore, the LED must be in thermal equilibrium. In practice, the LED takes only a few seconds to reach thermal equilibrium. The ambient temperature must be monitored and if the temperature changes the spectrometer must be recalibrated.

## Summary

A new family of reusable pulse oximetry sensors has been developed. Based on the HP M1190A, HP's first reusable  $\text{SpO}_2$  sensor, these sensors can noninvasively monitor the blood oxygen levels of patients, a key vital sign. They are used primarily in operating rooms, recovery rooms, intensive-care units, and some general wards. The new sensor family covers all application areas and consists of the M1194A clip sensor (Fig. 27), the HP M1191A adult sensor with new wavelength (Fig. 28), the HP M1192A pediatric sensor (Fig. 12), and the HP M1193A neonatal sensor (Fig. 29).

## Acknowledgments

Many people were involved in this project. The authors would especially like to thank Dietrich Rogler for the industrial design of the sensors, Willi Keim and Peter Jansen of materials engineering for their excellent support, Martin Guenther for performing all the optical characteristics measurements, Gerhard Klamser for verifying the algorithm, Gerhard Lenke for organizing all the regulation tasks, and Otto Gentner for managing the clinical trials. Special thanks to Professor Dr. J. W. Severinghaus of the University of California Hospital in San Francisco for performing volunteer studies.





**Fig. 27.** HP M1194A clip sensor.



**Fig. 28.** HP M1191A adult sensor.



**Fig. 29.** HP M1193A neonatal sensor.

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# Protective Order

**IN THE UNITED STATES DISTRICT COURT  
 FOR THE DISTRICT OF DELAWARE**

APPLE INC.,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 22-1377-MN-JLH
v.	)	
	)	<b>JURY TRIAL DEMANDED</b>
MASIMO CORPORATION and	)	
SOUND UNITED, LLC,	)	
	)	
Defendants.	)	
<hr/>		
MASIMO CORPORATION,	)	
	)	
Counter-Claimant,	)	
	)	
v.	)	
	)	
APPLE INC.,	)	
	)	
Counter-Defendant.	)	
<hr/>		
APPLE INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 22-1378-MN-JLH
	)	
MASIMO CORPORATION and	)	<b>JURY TRIAL DEMANDED</b>
SOUND UNITED, LLC,	)	
	)	
Defendants.	)	
<hr/>		
MASIMO CORPORATION and	)	
CERCACOR LABORATORIES, INC.,	)	
	)	
Counter-Claimants,	)	
	)	
v.	)	
	)	
APPLE INC.,	)	
	)	
Counter-Defendant.	)	

**AGREED PROTECTIVE ORDER  
REGARDING THE DISCLOSURE AND USE OF DISCOVERY MATERIAL**

Plaintiff and Counter-Defendant Apple Inc. (“Plaintiff”), Defendants and Counter-Claimants Masimo Corporation and Sound United, LLC and Counter-Claimant Cercacor Laboratories, Inc. (together, “Masimo”) anticipate that documents, testimony, or information containing or reflecting confidential, proprietary, trade secret, and/or commercially sensitive information are likely to be disclosed or produced during the course of discovery, initial disclosures, and supplemental disclosures in these cases and request that the Court enter this Order setting forth the conditions for treating, obtaining, and using such information.

Pursuant to Rule 26(c) of the Federal Rules of Civil Procedure, the Court finds good cause for the following Agreed Protective Order Regarding the Disclosure and Use of Discovery Material (“Order” or “Protective Order”).

1. **PURPOSES AND LIMITATIONS**

(a) Protected Material designated under the terms of this Protective Order shall be used by a Receiving Party solely for these cases, and shall not be used directly or indirectly for any other purpose whatsoever.

(b) The Parties acknowledge that this Order does not confer blanket protections on all disclosures during discovery, or in the course of making initial or supplemental disclosures under Rule 26(a). Designations under this Order shall be made with care and shall not be made absent a good faith belief that the designated material satisfies the criteria set forth below. If it comes to a Producing Party’s attention that designated material does not qualify for protection at all, or does not qualify for the level of protection initially asserted, the Producing Party must promptly notify all other Parties that it is withdrawing or changing the designation.

(c) Other Proceedings. By entering this order and limiting the disclosure of information in these cases, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a request or motion that would require disclosure of another party's information designated "CONFIDENTIAL," "CONFIDENTIAL - ATTORNEYS' EYES ONLY," or "CONFIDENTIAL - OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE," pursuant to this Order shall promptly notify that party of the request or motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

## 2. DEFINITIONS

(a) "Affiliate" means any corporation, company, or other business entity over which a Party has the power to direct or cause the direction of the management, policies, or legal actions through: (1) at least 50% ownership of voting securities; or (2) contract; or (3) other means.

(b) "Discovery Material" means all items or information, including from any non-party, regardless of the medium or manner generated, stored, or maintained (including, among other things, testimony, transcripts, or tangible things) that are produced, disclosed, or generated in connection with discovery or Rule 26(a) disclosures in these cases.

(c) "Outside Counsel" means (i) outside counsel who appear on the pleadings as counsel for a Party and (ii) partners, associates, and staff of such counsel to whom it is reasonably necessary to disclose the information for this litigation.

(d) "Patents-in-suit" means U.S. Patent Nos. D735,131, D883,279, D947,842, D962,936, 10,076,257, 10,627,783, 10,942,491, 10,987,054, 11,106,352, 11,474,483, 10,912,501, 10,912,502, 10,945,648, 10,687,743, 10,687,745, 10,722,159, 7,761,127, 8,190,223, 10,736,507,

and 10,984,911 and any other patent asserted in these cases, as well as any related patents, patent applications, provisional patent applications, continuations, and/or divisionals.

(e) “Party” means any party to these cases, including all of its officers, directors, employees, consultants, vendors, retained experts, and outside counsel and their support staffs.

(f) “Producing Party” means any Party or non-party that discloses or produces any Discovery Material in these cases.

(g) “Protected Material” means any Discovery Material that is designated as “CONFIDENTIAL,” “CONFIDENTIAL - ATTORNEYS’ EYES ONLY,” or “CONFIDENTIAL - OUTSIDE ATTORNEYS’ EYES ONLY - SOURCE CODE,” as provided for in this Order. Protected Material shall not include: (i) advertising materials that have been actually published or publicly disseminated; and (ii) materials that show on their face they have been disseminated to the public.

(h) “Receiving Party” means any Party who receives Discovery Material from a Producing Party.

(i) “Source Code” means computer code, scripts, assembly, binaries, object code, source code listings (e.g., file names and path structure), descriptions of source code (e.g., descriptions of declarations, functions, and parameters), object code listings and descriptions of object code, Hardware Description Language (HDL) or Register Transfer Level (RTL) files that describe the hardware design of any ASIC or other chip, and native Computer Aided Design (CAD) files that describe the hardware design of any component, the disclosure of which to another Party or non-party is likely to cause harm or competitive disadvantage to the Producing Party. To avoid any doubt, still images of CAD files are not Source Code and will not be subject to the

disclosure and review restrictions in Section 11. Still images of CAD files may be designated as “CONFIDENTIAL” or “CONFIDENTIAL - ATTORNEYS’ EYES ONLY,” as provided for in this Order.

3. **COMPUTATION OF TIME**

The computation of any period of time prescribed or allowed by this Order shall be governed by the provisions for computing time set forth in Federal Rules of Civil Procedure 6.

4. **SCOPE**

(a) The protections conferred by this Order cover not only Discovery Material governed by this Order as addressed herein, but also any information copied or extracted therefrom, as well as all copies, excerpts, summaries, or compilations thereof, plus testimony, conversations, or presentations by Parties or their counsel in court or in other settings that might reveal Protected Material.

(b) Nothing in this Protective Order shall prevent or restrict a Producing Party’s own disclosure or use of its own Protected Material for any purpose, and nothing in this Order shall preclude any Producing Party from showing its Protected Material to an individual who prepared the Protected Material.

(c) Nothing in this Order shall be construed to prejudice any Party’s right to use any Protected Material with the consent of the Producing Party or by order of the Court.

(d) This Order is without prejudice to the right of any Party to seek further or additional protection of any Discovery Material or to modify this Order in any way, including, without limitation, an order that certain matter not be produced at all.

(e) Any use of Protected Material at trial shall be governed by the orders of the trial judge and other applicable authorities. This Order does not govern the use of Protected Material at trial.

5. **DURATION**

Even after the termination of these cases, the confidentiality obligations imposed by this Order shall remain in effect until a Producing Party agrees otherwise in writing or a court order otherwise directs.

6. **ACCESS TO AND USE OF PROTECTED MATERIAL**

(a) **Basic Principles.** All Protected Material shall be used solely for these cases or any related appellate proceedings, and not for any other purpose whatsoever, including without limitation, any other litigation, patent prosecution or acquisition, patent reexamination or reissue proceedings, or any business or competitive purpose or function. Protected Material shall not be distributed, disclosed, or made available to anyone except as expressly provided in this Order.

(b) **Patent Prosecution Bar.** After the adoption of this provision by the parties, Outside Counsel and any person associated with a Party who receives a Producing Party's material designated "CONFIDENTIAL – ATTORNEYS' EYES ONLY" or "CONFIDENTIAL – ATTORNEYS' EYES ONLY – SOURCE CODE" under this Protective Order or who has access to, accesses, or otherwise learns of, in whole or in part, said material designated "CONFIDENTIAL – ATTORNEYS' EYES ONLY" or "CONFIDENTIAL – ATTORNEYS' EYES ONLY – SOURCE CODE" under this Protective Order shall not prepare, prosecute, supervise, advise, counsel, or assist in the preparation or prosecution of any patent application seeking a patent on behalf of the Receiving Party or its acquirer, successor, predecessor, or Affiliate in the field of non-invasive monitoring and/or consumer wearables (generally or as

described in any patent in suit) during the pendency of this Action and for two years after final termination of this action, including all appeals. To avoid any doubt, “prosecution” as used in this section does not include representing or advising a Party before a domestic or foreign agency in connection with a reissue, ex parte reexamination, covered business method review, inter partes review, opposition, cancellation, or similar proceeding; though in connection with any such foreign or domestic agency proceeding involving the patents-in-suit, any attorney who has access to, accesses, obtains, receives, or otherwise learns, in whole or in part, any other Party’s “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” or “CONFIDENTIAL – ATTORNEYS’ EYES ONLY – SOURCE CODE” shall not: (i) participate in the preparation, prosecution, supervision, advice, counsel, or assistance of any amended claims; (ii) reveal a Producing Party’s Protected Material to any prosecuting reexamination counsel or agent; or (iii) use a Producing Party’s Protected Material for any purpose not permitted by Section 1.

(c) Secure Storage, No Export. Protected Material must be stored and maintained by a Receiving Party at a location in the United States and in a secure manner that ensures that access is limited to the persons authorized under this Order. To ensure compliance with applicable United States Export Administration Regulations, Protected Material may not be exported outside the United States or released to any foreign national, even if within the United States. This applies to such information regardless of whether it is in the form of a stand-alone document or as an exhibit, attachment, or appendix to anything, including but not limited to briefs, reports, letters to counsel, discovery responses, or court filings—whether drafts or final versions. Foreign nationals shall not include the Parties’ Outside Counsel who reside in the United States, agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A, and who are identified in writing to the Producing Party. However, the Parties’ Outside Counsel



may access briefs, reports, letters to counsel, discovery responses, and court filings (including drafts) that contain Protected Material for purposes of working on these cases while traveling temporarily outside the United States, exclusive of any exhibits or appendices that attach or substantially reproduce or summarize documents, data, or testimony that have been designated by any other party as Protected Material. The Parties will use their best efforts to minimize the amount of Protected Materials in those documents (including without limitation by redacting references to Protected Materials that are not necessary for the work performed outside of the United States) to help ensure the security of the Parties' Protected Materials. Also, if this case eventually requires depositions or experts located outside the United States, the parties will revisit this issue and attempt to agree about exporting specific materials to the extent necessary. The Parties agree that neither Party waives the right to seek amendment of this Protective Order by the Court, following a meet and confer, if other circumstances concerning exportation arise in this case.

(d) Legal Advice Based on Protected Material. Nothing in this Protective Order shall be construed to prevent counsel from advising their clients with respect to these cases based in whole or in part upon Protected Materials, provided counsel does not disclose the Protected Material itself except as provided in this Order.

(e) Limitations. Nothing in this Order shall restrict in any way a Producing Party's use or disclosure of its own Protected Material. Nothing in this Order shall restrict in any way the use or disclosure of Discovery Material by a Receiving Party: (i) that is or has become publicly known through no fault of the Receiving Party; (ii) that is lawfully acquired by or known to the Receiving Party independent of the Producing Party; (iii) previously produced, disclosed and/or provided by the Producing Party to the Receiving Party or a non-party without an

obligation of confidentiality and not by inadvertence or mistake; (iv) with the consent of the Producing Party; or (v) pursuant to order of the Court.

7. **DESIGNATING PROTECTED MATERIAL**

(a) Available Designations. Any Producing Party may designate Discovery Material with any of the following designations, provided that it meets the requirements for such designations as provided for herein: “CONFIDENTIAL,” “CONFIDENTIAL - ATTORNEYS’ EYES ONLY,” or “CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY - SOURCE CODE.”

(b) Written Discovery and Documents and Tangible Things. Written discovery, documents (which include “electronically stored information,” as that phrase is used in Federal Rule of Procedure 34), and tangible things that meet the requirements for the confidentiality designations listed in Section 7(a) may be so designated by placing the appropriate designation on every page of the written material prior to production. For digital files being produced, the Producing Party may mark each viewable page or image with the appropriate designation, and mark the medium, container, and/or communication in which the digital files were contained. In the event that original documents are produced for inspection, the original documents shall be presumed “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” during the inspection and re-designated, as appropriate during the copying process.

(c) Native Files. Where electronic files and documents are produced in native electronic format, such electronic files and documents shall be designated for protection under this Order by appending to the file names or designators information indicating whether the file contains “CONFIDENTIAL,” “CONFIDENTIAL - ATTORNEYS’ EYES ONLY,” or “CONFIDENTIAL - OUTSIDE ATTORNEYS’ EYES ONLY - SOURCE CODE,” material, or

shall use any other reasonable method for so designating Protected Materials produced in electronic format. When electronic files or documents are printed for use at deposition, in a court proceeding, or for provision in printed form to an expert or consultant pre-approved pursuant to Section 12, the party printing the electronic files or documents shall affix a legend to the printed document corresponding to the designation of the Producing Party and including the production number and designation associated with the native file. The parties reserve the right to object to the use of any image format version of a document produced in native format to the extent any information has been altered.

(d) Depositions and Testimony. Parties or testifying persons or entities may designate depositions and other testimony with the appropriate designation by indicating on the record at the time the testimony is given or by sending written notice of how portions of the transcript of the testimony are designated within fifteen (15) days of receipt of the transcript of the testimony. If no indication on the record is made, all information disclosed during a deposition shall be deemed “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” until the time within which it may be appropriately designated as provided for herein has passed. Any Protected Material that is used in the taking of a deposition shall remain subject to the provisions of this Protective Order, along with the transcript pages of the deposition testimony dealing with such Protected Material. In such cases the court reporter shall be informed of this Protective Order and shall be required to operate in a manner consistent with this Protective Order. In the event the deposition is videotaped, the original and all copies of the videotape shall be marked by the video technician to indicate that the contents of the videotape are subject to this Protective Order, substantially along the lines of “This videotape contains confidential testimony used in this case and is not to be viewed or the contents thereof to be displayed or revealed except pursuant to the terms of the operative

Protective Order in this matter or pursuant to written stipulation of the parties.” Counsel for any Producing Party shall have the right to exclude from oral depositions, other than the deponent, deponent’s counsel, the reporter and videographer (if any), any person who is not authorized by this Protective Order to receive or access Protected Material based on the designation of such Protected Material. Such right of exclusion shall be applicable only during periods of examination or testimony regarding such Protected Material.

8. **DISCOVERY MATERIAL DESIGNATED AS “CONFIDENTIAL”**

(a) A Producing Party may designate Discovery Material as “CONFIDENTIAL” if it contains or reflects confidential, proprietary, and/or commercially sensitive information.

(b) Unless otherwise ordered by the Court, Discovery Material designated as “CONFIDENTIAL” may be disclosed only to the following:

(i) The Receiving Party’s Outside Counsel, such counsel’s immediate paralegals and staff, and any copying or clerical litigation support services working at the direction of such counsel, paralegals, and staff;

(ii) Officers or employees of the Receiving Party, who may be, but need not be, in-house counsel for the Receiving Party, as well as their immediate paralegals and staff, to whom disclosure is reasonably necessary for this case, provided that each such person has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A;

(iii) Any outside expert or consultant retained by the Receiving Party to assist in these cases, provided that disclosure is only to the extent necessary to perform such work; and provided that: (a) such expert or consultant has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A; (b) such expert or consultant is not a current

officer, director, or employee of a Party or of a competitor of a Party, nor anticipated at the time of retention to become an officer, director or employee of a Party or of a competitor of a Party; (c) such expert or consultant accesses the materials in the United States only, and does not transport them to or access them from any foreign jurisdiction (however, to avoid doubt, such expert or consultant may access reports (including drafts) that contain the materials for purposes of working on these cases while traveling temporarily outside the United States); and (d) no unresolved objections to such disclosure exist after proper notice has been given to all Parties as set forth in Section 12 below;

(iv) Witnesses at depositions or hearings in these cases and the witnesses' counsel, provided however that the disclosure shall only be made to: (1) a witness who is an employee of the Producing Party, or identified on the document as an author, addressee, or recipient of the material in question, or if there are other indicia (such as from metadata, cover emails, or other records of distribution) that the witness has seen or had access to the document previously; or (2) a witness who has been designated to testify on behalf of the Producing Party on the subject matter of the material in question, provided however that the Protected Material shown to such a witness shall be limited to Protected Material of the Producing Party;

(v) Court reporters, stenographers and videographers retained to record testimony taken in these cases, and their staff;

(vi) The Court, jury, and court personnel;

(vii) Graphics, translation, design, trial consulting personnel, and/or other professional vendors, having first agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A;

(viii) Mock jurors having first agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A.

(ix) Any mediator who is assigned to hear these matters, and his or her staff, subject to their agreement to maintain confidentiality to the same degree as required by this Protective Order; and

(x) Any other person with the prior written consent of the Producing Party.

9. **DISCOVERY MATERIAL DESIGNATED AS “CONFIDENTIAL – ATTORNEYS’ EYES ONLY”**

(a) A Producing Party may designate Discovery Material as “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” if it contains or reflects information that is extremely confidential and/or sensitive in nature and the Producing Party reasonably believes that the disclosure of such Discovery Material is likely to cause harm or significant competitive disadvantage to the Producing Party. The Parties agree that the following information, if non-public, shall be presumed to merit the “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” designation: trade secrets, pricing information, financial data, sales information, sales or marketing forecasts or plans, business plans, sales or marketing strategy, product development information, engineering documents, testing documents, employee information, and other non-public information of similar competitive and business sensitivity.

(b) Unless otherwise ordered by the Court, Discovery Material designated as “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” may be disclosed only to:

(i) The Receiving Party’s Outside Counsel, provided that such Outside Counsel is not involved in competitive decision-making, as defined by *U.S. Steel v. United States*, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984), on behalf of a Party or a competitor of a Party, and such

Outside Counsel's immediate paralegals and staff, and any copying or clerical litigation support services working at the direction of such counsel, paralegals, and staff;

(ii) Any outside expert or consultant retained by the Receiving Party to assist in this action, provided that disclosure is only to the extent necessary to perform such work; and provided that: (a) such expert or consultant has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A; (b) such expert or consultant is not a current officer, director, or employee of a Party or of a competitor of a Party, nor anticipated at the time of retention to become an officer, director, or employee of a Party or of a competitor of a Party; (c) such expert or consultant is not involved in competitive decision-making, as defined by *U.S. Steel v. United States*, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984), on behalf of a Party or a competitor of a Party; (d) such expert or consultant accesses the materials in the United States only, and does not transport them to or access them from any foreign jurisdiction (however, to avoid doubt, such expert or consultant may access reports (including drafts) that contain the materials for purposes of working on these cases while traveling temporarily outside the United States); and (e) no unresolved objections to such disclosure exist after proper notice has been given to all Parties as set forth in Section 12 below;

(iii) Witnesses at depositions or hearings in these cases and the witnesses' counsel, provided however that the disclosure shall only be made to: (1) a witness who is identified on the document as an author, addressee, or recipient of the material in question, or if there are other indicia (such as from testimony, metadata, cover emails, or other records of distribution) that the witness has previously seen or had access to the document or the information contained therein; or (2) a witness who has been designated to testify on behalf of the Producing Party on the subject matter of the material in question, provided however that

the Protected Material shown to such a witness shall be limited to Protected Material of the Producing Party;

(iv) Court reporters, stenographers and videographers retained to record testimony taken in this action, and their staff;

(v) The Court, jury, and court personnel;

(vi) Graphics, translation, design, trial consulting personnel, and/or other professional vendors, having first agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A;

(vii) Any mediator who is assigned to hear this matter, and his or her staff, subject to their agreement to maintain confidentiality to the same degree as required by this Protective Order; and

(viii) Any other person with the prior written consent of the Producing Party.

(c) In addition, a Party may disclose arguments and materials derived from Discovery Material designated as “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” to mock jurors who have signed an undertaking or agreement agreeing not to publicly disclose Protected Material and to keep any information concerning Protected Material confidential. A Party may not disclose to mock jurors any original, as-produced materials or information (including, for example, documents, deposition testimony, or interrogatory responses) produced by another Party designated as “CONFIDENTIAL - ATTORNEYS’ EYES ONLY.”

10. **DISCOVERY MATERIAL DESIGNATED AS “CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY - SOURCE CODE”**

(a) To the extent production of Source Code becomes necessary to the prosecution or defense of the cases, a Producing Party may designate Source Code as



“CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY - SOURCE CODE” if it comprises or includes confidential, proprietary, and/or trade secret Source Code.

(b) Nothing in this Order shall be construed as a representation or admission that Source Code is properly discoverable in these cases, or to obligate any Party to produce any Source Code.

(c) Unless otherwise ordered by the Court, Discovery Material designated as “CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY - SOURCE CODE” shall be subject to the provisions set forth in Section 11 below, and may be disclosed, subject to Section 11 below, solely to:

(i) The Receiving Party’s Outside Counsel, provided that such Outside Counsel is not involved in competitive decision-making, as defined by *U.S. Steel v. United States*, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984), on behalf of a Party or a competitor of a Party, and such Outside Counsel’s immediate paralegals and staff, and any copying or clerical litigation support services working at the direction of such counsel, paralegals, and staff;

(ii) Any outside expert or consultant retained by the Receiving Party to assist in this action, provided that disclosure is only to the extent necessary to perform such work; and provided that: (a) such expert or consultant has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A; (b) such expert or consultant is not a current officer, director, or employee of a Party or of a competitor of a Party, nor anticipated at the time of retention to become an officer, director or employee of a Party or of a competitor of a Party; (c) such expert or consultant is not involved in competitive decision-making, as defined by *U.S. Steel v. United States*, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984), on behalf of a Party or a competitor of a Party; (d) such expert or consultant accesses the materials in the United States only, and does not

transport them to or access them from any foreign jurisdiction; and (e) no unresolved objections to such disclosure exist after proper notice has been given to all Parties as set forth in Section 12 below;

(iii) Witnesses at depositions or hearings in these cases and the witnesses' counsel, provided however that the disclosure shall only be made to: (1) a witness who is identified on the material as an author, addressee, or recipient of the material, or if there are indicia (such as from testimony, metadata, emails, or other records of distribution) that the witness has seen or had access to the materials previously; or (2) a witness who has been designated to testify on behalf of the Producing Party on the subject matter of the material in question, provided however that the Protected Material shown to such a witness shall be limited to Protected Material of the Producing Party;

(iv) Court reporters, stenographers and videographers retained to record testimony taken in this action, and their staff;

(v) The Court, jury, and court personnel;

(vi) Any mediator who is assigned to hear this matter, and his or her staff, subject to their agreement to maintain confidentiality to the same degree as required by this Protective Order; and

(vii) Any other person with the prior written consent of the Producing Party.

#### 11. **DISCLOSURE AND REVIEW OF SOURCE CODE**

(a) Any Source Code that is produced by Plaintiff will be made available for inspection at the San Francisco office of its outside counsel, Desmarais LLP, or any other location mutually agreed by the Parties. Any Source Code that is produced by Masimo will be made

available for inspection at the Orange County office of their outside counsel, Knobbe Martens Olsen & Bear LLP, or any other location mutually agreed by the Parties. Source Code will be made available for inspection between the hours of 8 a.m. and 6 p.m. on business days (i.e., weekdays that are not Federal holidays), although the Parties will be reasonable in accommodating reasonable requests to conduct inspections at other times.

(b) Prior to the first inspection of any requested Source Code, the Receiving Party shall provide ten (10) days' notice of its intent to review the Source Code that has been made available by the Producing Party and, if known, the specific Source Code the Receiving Party intends to inspect. The Receiving Party shall provide seven (7) days' notice prior to any additional inspections.

(c) Source Code that is designated "CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE" shall be produced for inspection and review subject to the following provisions, unless otherwise agreed by the Producing Party:

(i) All Source Code shall be made available by the Producing Party to the Receiving Party's Outside Counsel and/or experts in a secure room on a secured computer without Internet access or network access to other computers and on which all access ports have been disabled (except for one printer port), as necessary and appropriate to prevent and protect against any unauthorized copying, transmission, removal or other transfer of any Source Code outside or away from the computer on which the Source Code is provided for inspection (the "Source Code Computer" in the "Source Code Review Room"). The Producing Party shall install tools that are sufficient for viewing and searching the code produced, on the platform produced, if such tools exist and are presently used in the ordinary course of the Producing Party's business. The Receiving Party's Outside Counsel and/or experts may request that commercially available

software tools for viewing and searching Source Code be installed on the secured computer, provided, however, that (a) the Receiving Party possesses an appropriate license to such software tools; (b) the Producing Party approves such software tools (approvals will not be unreasonably denied); and (c) such other software tools are reasonably necessary for the Receiving Party to perform its review of the Source Code consistent with all of the protections herein. The Receiving Party must provide the Producing Party with the CD or DVD or other media containing such licensed software tool(s) at least seven (7) days in advance of the date upon which the Receiving Party wishes to have the additional software tools available for use on the Source Code Computer.

(ii) No recordable media or recordable devices, including without limitation sound recorders, computers, cellular telephones, peripheral equipment, cameras, CDs, DVDs, or drives of any kind, shall be permitted into the Source Code Review Room.

(iii) The Receiving Party's Outside Counsel and/or experts shall be entitled to take notes relating to the Source Code but may not copy the Source Code into the notes and may not take such notes electronically on the Source Code Computer itself or any other computer.

(iv) The Producing Party may visually monitor the activities of the Receiving Party's representatives during any Source Code review, but only to ensure that no unauthorized electronic records of the Source Code and no information concerning the Source Code are being created or transmitted in any way.

(v) No copies of all or any portion of the Source Code may leave the room in which the Source Code is inspected except as otherwise provided herein. Further, no other written or electronic record of the Source Code is permitted except as otherwise provided herein. The Producing Party shall make available a laser printer with commercially reasonable

printing speeds for on-site printing during inspection of the Source Code. The Receiving Party may print limited portions of the Source Code only when necessary to prepare court filings or pleadings or other papers (including a testifying expert's expert report). The Receiving Party may print the Source Code in 12-point font and with information necessary to later identify that Source Code, such as, but not limited to, a header or footer, that identifies the file name and directory path. Any printed portion that consists of more than fifteen (15) pages of a continuous block of Source Code shall be presumed to be excessive, and the burden shall be on the Receiving Party to demonstrate the need for such a printed copy. The Receiving Party may print out no more than 200 pages total without prior agreement from the Producing Party or order of the Court. The Receiving Party shall not print Source Code in order to review blocks of Source Code elsewhere in the first instance, i.e., as an alternative to reviewing that Source Code electronically on the Source Code Computer, as the Parties acknowledge and agree that the purpose of the protections herein would be frustrated by printing portions of code for review and analysis elsewhere, and that printing is permitted only when necessary to prepare court filings or pleadings or other papers (including a testifying expert's expert report). Upon printing any such portions of Source Code, the printed pages shall be collected by the Producing Party. The Producing Party shall Bates number, copy, and label "CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE" any pages printed by the Receiving Party. Within seven (7) days, the Producing Party shall either (i) provide one copy set of such pages to the Receiving Party or (ii) inform the Requesting Party that it objects that the printed portions are excessive and/or not done for a permitted purpose. If, after meeting and conferring, the Producing Party and the Receiving Party cannot resolve the objection, the Receiving Party shall be entitled to seek a Court resolution of whether the printed Source Code in question is narrowly tailored and was printed for a permitted purpose. The

burden shall be on the Receiving Party to demonstrate that such printed portions are no more than is reasonably necessary for a permitted purpose and not merely printed for the purposes of review and analysis elsewhere. The printed pages shall constitute part of the Source Code produced by the Producing Party in these cases.

(vi) All persons who will review a Producing Party's Source Code on behalf of a Receiving Party, including members of a Receiving Party's outside law firm, shall be identified in writing to the Producing Party at least five (5) days in advance of the first time that such person reviews such Source Code. Such identification shall be in addition to any other disclosure required under this Order. All persons viewing Source Code shall sign on each day they view Source Code a log that will include the names of persons who enter the locked room to view the Source Code and when they enter and depart. The Producing Party shall be entitled to a copy of the log upon one (1) day's advance notice to the Receiving Party.

(vii) Unless otherwise agreed in advance by the Parties in writing, following each day on which inspection is done under this Order, the Receiving Party's Outside Counsel and/or experts shall remove all notes, documents, and all other materials from the Source Code Review Room. The Producing Party shall not be responsible for any items left in the room following each inspection session, and the Receiving Party shall have no expectation of confidentiality for any items left in the room following each inspection session without a prior agreement to that effect. Proper identification of all authorized persons shall be provided prior to any access to the secure room or the computer containing Source Code. Proper identification requires showing, at a minimum, a photo identification card sanctioned by the government of any State of the United States, by the government of the United States, or by the nation state of the authorized person's current citizenship. Access to the secure room or the Source Code Computer

may be denied, at the discretion of the supplier, to any individual who fails to provide proper identification.

(viii) Other than as provided above, the Receiving Party will not copy, remove, or otherwise transfer any Source Code from the Source Code Computer including, without limitation, copying, removing, or transferring the Source Code onto any recordable media or recordable device. The Receiving Party will not transmit any Source Code in any way from the Producing Party's facilities or the offices of its Outside Counsel of record.

(ix) The Receiving Party's Outside Counsel of record may make no more than three (3) additional paper copies of any portions of the Source Code received from a Producing Party pursuant to Section 11(c)(v), not including copies attached to court filings or used at depositions, and shall maintain a log of all paper copies of the Source Code. The log shall include the names of the reviewers and/or recipients of paper copies and locations where the paper copies are stored. Upon one (1) day's advance notice to the Receiving Party by the Producing Party, the Receiving Party shall provide a copy of this log to the Producing Party.

(x) The Receiving Party's Outside Counsel of record and any person receiving a copy of any Source Code shall maintain and store any paper copies of the Source Code at their offices in a manner that prevents duplication of or unauthorized access to the Source Code, including, without limitation, storing the Source Code in a locked room or cabinet at all times when it is not in use. No more than a total of fifteen (15) individuals identified by the Receiving Party shall have access to the printed portions of Source Code (except insofar as such code appears in any court filing or expert report).

(xi) For depositions, the Receiving Party shall not bring copies of any printed Source Code. Rather, at least seven (7) days before the date of the deposition, the Receiving

Party shall notify the Producing Party about the specific portions of Source Code it wishes to use at the deposition, and the Producing Party shall bring printed copies of those portions to the deposition for use by the Receiving Party. The Producing Party shall also accommodate reasonable requests from the Receiving Party to make a Source Code Computer available at the deposition for use at the deposition. Copies of Source Code that are marked as deposition exhibits shall not be provided to the Court Reporter or attached to deposition transcripts; rather, the deposition record will identify the exhibit by its production numbers. All paper copies of Source Code brought to the deposition shall remain with the Producing Counsel's Outside Counsel for secure destruction in a timely manner following the deposition.

(xii) Except as provided in this section, absent express written permission from the Producing Party, the Receiving Party may not create electronic images, or any other images, or make electronic copies, of the Source Code from any paper copy of Source Code for use in any manner (including by way of example only, the Receiving Party may not scan the Source Code to a PDF or photograph the code). Images or copies of Source Code shall not be included in correspondence between the Parties (references to production numbers shall be used instead), and shall be omitted from pleadings and other papers whenever possible. If a Party reasonably believes that it needs to submit a portion of Source Code as part of a filing with the Court, the Parties shall meet and confer as to how to make such a filing while protecting the confidentiality of the Source Code and such Source Code will not be filed absent agreement from the Producing Party that the confidentiality protections will be adequate. If a Producing Party agrees to produce an electronic copy of all or any portion of its Source Code or provide written permission to the Receiving Party that an electronic or any other copy needs to be made for a Court filing, access to the Receiving Party's submission, communication, and/or disclosure of electronic files or other materials



containing any portion of Source Code (paper or electronic) shall at all times be limited solely to individuals who are expressly authorized to view Source Code under the provisions of this Order. Where the Producing Party has provided the express written permission required under this provision for a Receiving Party to create electronic copies of Source Code, the Receiving Party shall maintain a log of all such electronic copies of any portion of Source Code in its possession or in the possession of its retained consultants, including the names of the reviewers and/or recipients of any such electronic copies, and the locations and manner in which the electronic copies are stored. Additionally, any such electronic copies must be labeled “CONFIDENTIAL - ATTORNEYS’ EYES ONLY - SOURCE CODE” as provided for in this Order.

12. **NOTICE OF DISCLOSURE**

(a) Prior to disclosing any Protected Material to any person described in Sections 8(b)(iii), 9(b)(ii), or 10(c)(ii) (referenced below as “Person”), the Party seeking to disclose such information shall provide the Producing Party with written notice that includes:

- (i) the name of the Person;
- (ii) an up-to-date curriculum vitae of the Person;
- (iii) the present employer and title of the Person;
- (iv) an identification of all of the Person’s past and current employment and consulting relationships in the past five years, including direct relationships and relationships through entities owned or controlled by the Person, including but not limited to an identification of any individual or entity with or for whom the person is employed or to whom the person provides consulting services relating to the design, development, operation, or patenting of technologies relating to non-invasive monitoring and/or consumer wearables (generally or as described in any patent in suit), or relating to the acquisition of intellectual property assets relating

to non-invasive monitoring and/or consumer wearables (generally or as described in any patent in suit);

(v) an identification of all pending patent applications on which the Person is named as an inventor, in which the Person has any ownership interest, or as to which the Person has had or anticipates in the future any involvement in advising on, consulting on, preparing, prosecuting, drafting, editing, amending, or otherwise affecting the scope of the claims; and

(vi) a list of the cases in which the Person has testified at deposition or trial within the last five (5) years.

Further, the Party seeking to disclose Protected Material shall provide such other information regarding the Person's professional activities reasonably requested by the Producing Party for it to evaluate whether good cause exists to object to the disclosure of Protected Material to the outside expert or consultant.

(b) Within ten (10) days of receipt of the disclosure of the Person, the Producing Party or Parties may object in writing to the Person for good cause. In the absence of an objection at the end of the ten (10) day period, the Person shall be deemed approved under this Protective Order. There shall be no disclosure of Protected Material to the Person prior to expiration of this ten (10) day period. If the Producing Party objects to disclosure to the Person within such ten (10) day period, the Parties shall meet and confer via telephone or in person within four (4) days following the objection and attempt in good faith to resolve the dispute on an informal basis. If the dispute is not resolved, the Party objecting to the disclosure will have four (4) days from the date of the meet and confer to seek relief from the Court and shall have the burden of proving the need for a protective order. If relief is not sought from the Court within that time, the objection

shall be deemed withdrawn. If relief is sought, designated materials shall not be disclosed to the Person in question until the Court resolves the objection.

(c) For purposes of this section, “good cause” shall include an objectively reasonable concern that the Person will, advertently or inadvertently, use or disclose Discovery Material in a way or ways that are inconsistent with the provisions contained in this Order.

(d) Prior to receiving any Protected Material under this Order, the Person must execute a copy of the “Agreement to Be Bound by Protective Order” (Exhibit A hereto) and serve it on all Parties.

(e) An initial failure to object to a Person under this Section 12 shall not preclude the nonobjecting Party from later objecting to continued access by that Person for good cause. If an objection is made, the Parties shall meet and confer via telephone or in person within seven (7) days following the objection and attempt in good faith to resolve the dispute informally. If the dispute is not resolved, the Party objecting to the disclosure will have seven (7) days from the date of the meet and confer to seek relief from the Court. The designated Person may continue to have access to information that was provided to such Person prior to the date of the objection. If a later objection is made, no further Protected Material shall be disclosed to the Person until the Court resolves the matter or the Producing Party withdraws its objection. Notwithstanding the foregoing, if the Producing Party fails to move for a protective order within seven (7) business days after the meet and confer, further Protected Material may thereafter be provided to the Person.

13. **CHALLENGING DESIGNATIONS OF PROTECTED MATERIAL**

(a) A Party shall not be obligated to challenge the propriety of any designation of Discovery Material under this Order at the time the designation is made, and a failure to do so shall not preclude a subsequent challenge thereto.

(b) Any challenge to a designation of Discovery Material under this Order shall be written, shall be served on Outside Counsel for the Producing Party, shall particularly identify the documents or information that the Receiving Party contends should be differently designated, and shall state the grounds for the objection. Thereafter, further protection of such material shall be resolved in accordance with the following procedures:

(i) The objecting Party shall have the burden of conferring either in person, in writing, or by telephone with the Producing Party claiming protection (as well as any other interested party) in a good faith effort to resolve the dispute. The Producing Party shall have the burden of justifying the disputed designation;

(ii) Failing agreement, the Receiving Party may bring a request or motion to the Court for a ruling that the Discovery Material in question is not entitled to the status and protection of the Producing Party's designation. The Parties' entry into this Order shall not preclude or prejudice either Party from arguing for or against any designation, establish any presumption that a particular designation is valid, or alter the burden of proof that would otherwise apply in a dispute over discovery or disclosure of information;

(iii) Notwithstanding any challenge to a designation, the Discovery Material in question shall continue to be treated as designated under this Order until one of the following occurs: (a) the Party who designated the Discovery Material in question withdraws such designation in writing; or (b) the Court rules that the Discovery Material in question is not entitled to the designation.

14. **DATA SECURITY**

(a) The Receiving Party shall implement an information security management system ("ISMS") to safeguard Protected Materials, including reasonable and appropriate

administrative, physical, and technical safeguards, and network security and encryption technologies governed by written policies and procedures, which shall comply with at least one of the following standards: (a) the International Organization for Standardization's 27001 standard; (b) the National Institute of Standards and Technology's (NIST) 800-53 standard; (c) the Center for Internet Security's Critical Security Controls, Version 8; or (d) the most recently published version of another widely recognized industry or government cybersecurity framework. The Parties shall implement encryption of all Protected Materials in transit outside of network(s) covered by the Party's ISMS (and at rest, where reasonably practical). Moreover, the Parties agree not to access Protected Materials from public computers.

(b) If the Receiving Party becomes aware of any unauthorized access, use, or disclosure of Protected Materials or devices containing Protected Materials ("Data Breach"), the Receiving Party shall promptly, and in no case later than 48 hours after learning of the Data Breach, notify the Producing Party in writing and fully cooperate with the Producing Party as may be reasonably necessary to (a) determine the source, extent, or methodology of such Data Breach, (b) recover or protect Protected Materials, and/or (c) to satisfy the Producing Party's legal, contractual, or other obligations. For the avoidance of doubt, notification obligations under this section arise when the Receiving Party both (a) learns of a Data Breach, and (b) learns that any of the Producing Party's Protected Materials are potentially subject to the Data Breach. The notification obligations set forth in this section do not run from the time the Data Breach itself.

(c) If the Receiving Party is aware of a Data Breach, the Parties shall meet and confer in good faith regarding any adjustments that should be made to the discovery process and discovery schedule in these cases, potentially including but not limited to (1) additional security measures to protect Discovery Material; (2) a stay or extension of discovery pending investigation

of a Data Breach and/or implementation of additional security measures; and (3) a sworn assurance that Discovery Material will be handled in the future only by entities not impacted by the Data Breach. In the event of a Data Breach affecting Protected Material of the Designating Party, at the Designating Party's request, the Receiving Party within 10 business days shall provide a copy of its most recent ISMS policies and procedures that relate to the safeguarding of Protected Materials and that preceded the Data Breach. Further, the Receiving Party shall submit to reasonable discovery concerning the Data Breach.

15. **SUBPOENAS OR COURT ORDERS**

(a) If at any time Protected Material is subpoenaed by any court, arbitral, administrative, or legislative body, the Party to whom the subpoena or other request is directed shall immediately give prompt written notice thereof to every Party who has produced such Discovery Material and to its counsel and shall provide each such Party with an opportunity to move for a protective order regarding the production of Protected Materials implicated by the subpoena. The Producing Party must also notify in writing the party who caused the subpoena or order to issue in the other litigation that some or all of the material covered by the subpoena or order is subject to this Protective Order, and include a copy of this Protective Order. The parties agree to work together to allow the Producing Party to seek a protective order, after the filing of which the Party served with the subpoena or court order shall not produce any information designated in this action as "CONFIDENTIAL – ATTORNEYS EYES ONLY" or "CONFIDENTIAL – ATTORNEYS EYES ONLY – SOURCE CODE" before a determination on the protective order by the court from which the subpoena or order issued, unless the Party has obtained the Producing Party's permission.

16. **FILING PROTECTED MATERIAL**

(a) Absent written permission from the Producing Party or a court Order secured after appropriate notice to all interested persons, a Receiving Party may not file or disclose in the public record any Protected Material.

(b) Any Party is authorized under District of Delaware Local Rule 5.1.3 to file under seal with the Court any brief, document or materials that are designated as Protected Material under this Order. However, nothing in this section shall in any way limit or detract from this Order's requirements as to Source Code.

17. **INADVERTENT DISCLOSURE OF PRIVILEGED MATERIAL**

(a) Pursuant to Federal Rule of Evidence 502(d) and (e), the inadvertent production by a Party of Discovery Material subject to the attorney-client privilege, work-product protection, or any other applicable privilege or protection, despite the Producing Party's reasonable efforts to prescreen such Discovery Material prior to production, will not waive the applicable privilege and/or protection in any other federal or state proceeding if a request for return of such inadvertently produced Discovery Material is made promptly after the Producing Party learns of its inadvertent production. For example, the mere production of a privileged or work product protected document in this case as part of a production is not itself a waiver. Nothing in this Order shall be interpreted to require disclosure of irrelevant information or relevant information protected by the attorney-client privilege, work product doctrine, or any other applicable privilege or immunity. The parties do not waive any objections as to the production, discoverability, admissibility, or confidentiality of documents and ESI. Moreover, nothing in this Order shall be interpreted to require disclosure of information subject to privacy protections as set forth in law or

regulation, including information that may need to be produced from outside of the United States and/or may be subject to foreign laws.

(b) Upon a request from any Producing Party who has inadvertently produced Discovery Material that it believes is privileged and/or protected, each Receiving Party shall immediately return such Protected Material or Discovery Material and all copies to the Producing Party, except for any pages containing privileged markings by the Receiving Party which shall instead be destroyed and certified as such by the Receiving Party to the Producing Party.

(c) Nothing herein shall prevent the Receiving Party from preparing a record for its own use containing the date, author, addresses, and topic of the inadvertently produced Discovery Material and such other information as is reasonably necessary to identify the Discovery Material and describe its nature to the Court in any motion to compel production of the Discovery Material.

18. **INADVERTENT FAILURE TO DESIGNATE PROPERLY**

(a) The inadvertent failure by a Producing Party to designate Discovery Material as Protected Material with one of the designations provided for under this Order shall not waive any such designation provided that the Producing Party notifies all Receiving Parties that such Discovery Material is protected under one of the categories of this Order within ten (10) days of the Producing Party learning of the inadvertent failure to designate. The Producing Party shall reproduce the Protected Material with the correct confidentiality designation within five (5) days upon its notification to the Receiving Parties. Upon receiving the Protected Material with the correct confidentiality designation, the Receiving Parties shall return or securely destroy, at the Producing Party's option, all Discovery Material that was not designated properly.

(b) A Receiving Party shall not be in breach of this Order for any use of such Discovery Material before the Receiving Party receives such notice that such Discovery Material



is protected under one of the categories of this Order, unless an objectively reasonable person would have realized that the Discovery Material should have been appropriately designated with a confidentiality designation under this Order. Once a Receiving Party has received notification of the correct confidentiality designation for the Protected Material with the correct confidentiality designation, the Receiving Party shall treat such Discovery Material (subject to the exception in Section 18(c) below) at the appropriately designated level pursuant to the terms of this Order.

(c) Notwithstanding the above, a subsequent designation of “CONFIDENTIAL,” “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” or “CONFIDENTIAL – ATTORNEYS’ EYES ONLY – SOURCE CODE” shall apply on a going forward basis and shall not disqualify anyone who reviewed “CONFIDENTIAL,” “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” or “CONFIDENTIAL – ATTORNEYS’ EYES ONLY – SOURCE CODE” materials while the materials were not marked “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” or “CONFIDENTIAL – ATTORNEYS’ EYES ONLY – SOURCE CODE” from engaging in the activities set forth in Section 6(b).

19. **INADVERTENT DISCLOSURE NOT AUTHORIZED BY ORDER**

(a) In the event of a disclosure of any Discovery Material pursuant to this Order to any person or persons not authorized to receive such disclosure under this Protective Order, the Party responsible for having made such disclosure, and each Party with knowledge thereof, shall immediately notify counsel for the Producing Party whose Discovery Material has been disclosed and provide to such counsel all known relevant information concerning the nature and circumstances of the disclosure. The responsible disclosing Party shall also promptly take all reasonable measures to retrieve the improperly disclosed Discovery Material and to ensure that no further or greater unauthorized disclosure and/or use thereof is made.

(b) Unauthorized or inadvertent disclosure does not change the status of Discovery Material or waive the right to hold the disclosed document or information as Protected.

20. **FINAL DISPOSITION**

(a) Not later than ninety (90) days after the Final Disposition of these cases, each Party shall return all Discovery Material of a Producing Party to the respective Outside Counsel of the Producing Party or destroy such Material, at the option of the Producing Party. For purposes of this Order, “Final Disposition” occurs after an order, mandate, or dismissal finally terminating these cases with prejudice, including all appeals.

(b) All Parties that have received any such Discovery Material shall certify in writing that all such materials have been returned to the respective Outside Counsel of the Producing Party or destroyed. Notwithstanding the provisions for return of Discovery Material, Outside Counsel may retain one set of pleadings, correspondence and attorney and consultant work product (but not document productions) for archival purposes, but must return any pleadings, correspondence, and consultant work product that contain Source Code.

21. **MISCELLANEOUS**

(a) Right to Further Relief. Nothing in this Order abridges the right of any person to seek its modification by the Court in the future. By stipulating to this Order, the Parties do not waive the right to argue that certain material may require additional or different confidentiality protections than those set forth herein.

(b) Termination of Matters and Retention of Jurisdiction. The Parties agree that the terms of this Protective Order shall survive and remain in effect after the Final Determination of the above-captioned matters. The Court shall retain jurisdiction after Final Determination of these matters to hear and resolve any disputes arising out of this Protective Order.

(c) Successors. This Order shall be binding upon the Parties hereto, their successors, and anyone, including law firms, who obtains access to Protected Material.

(d) Right to Assert Other Objections. By stipulating to the entry of this Protective Order, no Party waives any right it otherwise would have to object to disclosing or producing any information or item. Similarly, no Party waives any right to object on any ground to use in evidence of any of the material covered by this Protective Order. This Order shall not constitute a waiver of the right of any Party to claim in these cases or otherwise that any Discovery Material, or any portion thereof, is privileged or otherwise non-discoverable, or is not admissible in evidence in these cases or any other proceeding.

(e) Modification by Court. This Order is subject to further court order based upon public policy or other considerations, and the Court may modify this Order *sua sponte* in the interests of justice. The United States District Court for the District of Delaware is responsible for the interpretation and enforcement of this Order. All disputes concerning Protected Material, however designated, produced under the protection of this Order shall be resolved by the United States District Court for the District of Delaware.

POTTER ANDERSON & CORROON LLP

PHILLIPS MCLAUGHLIN & HALL, P.A.

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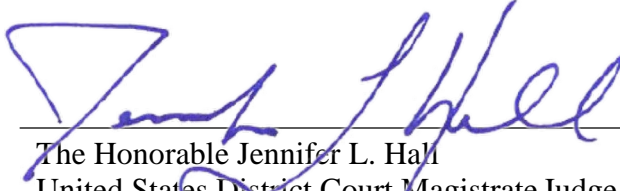
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*Attorneys for Defendants Masimo Corporation  
and Sound United, LLC*

*Attorneys for Plaintiff Apple Inc.*

Dated: June 14, 2023

IT IS SO ORDERED this 16th day of June, 2023.

  
\_\_\_\_\_  
The Honorable Jennifer L. Hall  
United States District Court Magistrate Judge

**EXHIBIT A**

I, \_\_\_\_\_, acknowledge and declare that I have received a copy of the Protective Order (“Order”) in *Apple Inc. v. Masimo Corp. et al.*, United States District Court, District of Delaware, C.A. Nos. 22-1377-MN-JLH and 22-1378-MN-JLH. Having read and understood the terms of the Order, I agree to be bound by the terms of the Order and consent to the jurisdiction of said Court for the purpose of any proceeding to enforce the terms of the Order.

Name of individual: \_\_\_\_\_

Present occupation/job description: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Name of Company or Firm: \_\_\_\_\_

Address: \_\_\_\_\_

Dated: \_\_\_\_\_

\_\_\_\_\_  
[Signature]

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